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(54) **SYSTEM FOR THREAD TRANSECTION OF A LIGAMENT**

SYSTEM ZUR FASERDURCHTRENNUNG EINES LIGAMENTS

SYSTÈME POUR COUPE TRANSVERSALE PAR FIL D'UN LIGAMENT

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Description

[0001] The present invention is generally directed to a surgical system for transecting soft tissue within a body. More particularly, the invention provides for the transection, by minimally invasive means, of a ligament such as for example the transverse carpal ligament that is commonly released as a treatment for carpal tunnel syndrome.

BACKGROUND

[0002] Many people suffer from injury to the soft tissues of the wrist and carpal tunnel, often caused by frequent, sustained repetitive motion involving the hands. Repetitive activities which require the same or similar hand/wrist action can result in injuries which have been collectively referred to as Cumulative Repetitive Stress Syndrome or Repetitive Strain Injury. The most familiar and common of such wrist injuries is known as carpal tunnel syndrome which produces pain, discomfort, nerve conduction disturbances, and impairment of function of the hand and sometimes the arm as well. The most common symptoms of this condition include intermittent pain and numbness of the hand.

[0003] Carpal tunnel syndrome occurs when the median nerve which runs from the forearm into the hand, becomes pressed or squeezed at the wrist. The median nerve provides feeling in one's thumb and along with index, middle and ring ringers. The median nerve controls sensations to the palmar side of the thumb and these fingers as well as impulses to some muscles in the hand which allow the fingers and thumb to move. The median nerve receives blood, oxygen and nutrients through a microvascular system which is present in the connective tissue surrounding the nerve fiber. Increased pressure on the nerve fiber can constrict these microvessels and will reduce the blood flow to the median nerve. Any prolonged deprivation of oxygen and nutrients can result in severe nerve damage.

[0004] The median nerve passes through the carpal tunnel, a canal in the wrist surrounded by the carpal bones on three sides and a fibrous sheath called the transverse carpal ligament on the fourth side. In addition to the median nerve, the nine flexor tendons in the hand pass through this canal. When compressed, the median nerve will cause pain, weakness or numbness in the hand and wrist which may also radiate up along he arm. The median nerve can be compressed by a decrease in the size of the carpal canal itself or an increase in the size of its contents (i.e. such as the swelling of the flexor tendons and of the lubrication tissue surrounding these flexor tendons), or both. For example, conditions that irritate or inflame the tendons can cause them to swell. The thickening of irritated tendons or swelling of other tissue within the canal narrows the carpal canal, causing the median nerve to be compressed. The cross-sectional area of the tunnel also changes when the hand and wrist changes positions. Wrist flexion or extension can decrease the cross-sectional area, thus increasing the pressure exerted on the median nerve. Flexion also causes the flexor tendons to somewhat rearrange which can also compress the median nerve. For example, simple bending of the wrist at a 90 degree angle will decrease the size of the carpal canal. Without treatment, carpal tunnel syndrome can lead to chronic neural muscular disorders of the hand and sometimes the arm.

[0005] Treatment for carpal tunnel syndrome includes a variety of non-surgical as well as surgical procedures, wherein carpal tunnel release is one of the most common surgical procedures that is performed. Such surgery involves the severing of the transverse carpal ligament to relieve the pressure on the median nerve and is commonly performed via either open or endoscopic methods. In open methods, the skin lying over the carpal tunnel is incised after which the transverse carpal ligament is transected under direct vision. The skin is then reapproximated with sutures. Endoscopic methods require incision of the skin in one or more locations to allow for the insertion of an endoscope along with various tools that are needed to transect the ligament. Such tools typically include a combination of a specially configured scalpel and guide instrument. The insertion of such tools into proper position below, above or both below and above the target ligament further requires the formation of one or more pathways in the hand with attendant trauma to the surrounding tissue and the potential for nerve damage as well as a more protracted post-surgical healing process. Additionally, the use of a scalpel typically requires multiple passes thereof in order to complete a transection which causes a complex pattern of cuts to be imparted onto the severed ligament surfaces.

[0006] Less invasive techniques have been proposed including for example the use of flexible saw elements that are introduced into the hand and positioned adjacent to or wrapped about a portion of the target ligament after which the saw element is reciprocated to cut the tissue. A substantial disadvantage of a cut that is made by a saw-like instrument as opposed to a knife-like instrument is inherent in the fact that a kerf is created. The material that is removed from the kerf is either deposited in and around the surgical site or additional steps must be taken to retrieve such material. Additionally, the cut surfaces that are created by a saw tend to be relatively rough and abraded with microtrauma on the cutting surface that may increase inflammatory response (edema, erythema, heat and pain), could result in local tissue adhesions and scarring which can delay or complicate the healing process.

[0007] US2011087255 discloses a system for releasing a ligament including a tubular body including a proximal end and a distal end and a proximal handle that is coupled to the proximal end. A flexible body extends through the tubular body and includes a tissue cutting portion. The flexible body is longitudinally displaceable relative to the tubular body to move the tissue cutting portion between a non-deployed state and a deployed

state. The tissue cutting portion includes a plurality of teeth or an abrasive surface.

[0008] US5522827 shows an apparatus and method for harvesting a tendon graft beneath overlying tissues. This is carried out through a remote incision which exposes only a portion of the donor tendon from which the graft will be harvested. The apparatus includes an elongated tubular shaft connected to a handle and a cutting element. A needle is connected to one end of the cutting element extending from the distal end of the shaft. The needle end of the cutting element is affixed to the distal end of the shaft to form a loop for slitting the tendon.

[0009] WO2011140206 relates to a surgical device for severing targeted tissues. It comprises a solid needle adapted to slidingly receive a hollow needle. The hollow needle includes a needle passage having a passage cross-sectional dimension. A surgical filament is operatively connected to the solid needle and it has a surgical cutting portion such as a metal wire coated with diamond particles.

[0010] Alternatively, techniques have been proposed wherein a taut wire, string or filament is used to cut a ligament. The cut is achieved either by the tautening of the cutting element or alternatively, by reciprocating the taut element. Disadvantages associated with such an approach are inherent in the less than optimal geometry by which a taut wire can be brought to bear on the target ligament and by the invasiveness of the tightening apparatus.

[0011] A new system is needed with which tissue such as a ligament can be percutaneously accessed and transected so as to cause a very minimal amount of disruption to the surrounding tissue and by which a smooth, kerf-less cut is achieved.

SUMMARY OF THE INVENTION AND FURTHER DISCLOSURE

[0012] The present invention provides a system for the minimally-invasive transection of tissue such as a ligament. The system obviate the need for any incisions, minimizes disruption of the tissue surrounding the target ligament, enables a smooth kerf-less cut of the target ligament to be achieved, requires no suturing and can be easily and quickly performed in a clinic setting. The system according to the invention is defined in claim 1. Preferred embodiments are defined in the dependent claims.

[0013] More particularly, the present disclosure further provides for the introduction of a thin and flexible thread-like cutting element into the body and its routing about the target ligament. Subsequent manipulation of the protruding ends of the smooth cutting element serves to transect the ligament by a smooth kerf-less cut. A routing tool component of the system according to the invention enables the cutting element to be easily and quickly introduced and routed into position about the target ligament with minimal disruption or trauma to the surrounding tissue. According to the present disclosure, the routing tool component may further take the form of a hollow introducer needle or a specially configured hooked retrieval needle comprising a thin, rigid and elongated needle-like element having near its distal end a hook-like feature formed therein that is dimensioned to engage the cutting element and configured to maintain engagement therewith when being pulled proximally.

[0014] In the transection of the transverse carpal ligament, the routing tool component is initially used to puncture the skin of the hand so as to form a first access port at a location proximal to the ligament and laterally adjacent thereto. The tool is then extended into the hand through the carpal tunnel along a path immediately below the ligament and is caused to emerge from the hand through a second access port formed thereby just distal to the ligament. The position of the routing tool in the hand and especially in relation to the ligament is preferably visualized throughout the placement procedure using for example an ultrasound imaging device to enable precise maneuvering of the tool.

[0015] Should a hooked retrieval needle serve as the routing tool and once it is in the position within the hand as is described above, a length of the cutting element is engaged by the hooking element of the retrieval needle and a loop thereof is drawn into the hand via the second access port. The zero bend radius of the cutting element allows the loop that is formed to be as compact as possible. The loop is drawn under the ligament and out of the first access port where it is disengaged from the retrieval needle and its free end pulled through. Reextension of the retrieval needle into the hand and along the top surface of the ligament to the second access port allows a second length of the cutting element to be engaged and a loop thereof drawn into the hand, over the ligament and out of the first access port. By pulling the second free end of the cutting element through the hand over the ligament and out of the first access port, the routing of the cutting element about the ligament is complete leaving the cutting element in position for the transection.

[0016] Should a hollow introducer needle serve as the router tool, the cutting element is inserted into the needle's proximal end while the needle is in the position described above. The cutting element is extended through the length of the needle and approximately one half of the cutting element is pulled from the distal end of the needle. The needle is then proximally retracted from the hand to leave the cutting element in place in the hand such that a sizable portion thereof protrudes from the first access port as well as from the second access port. The hollow needle is then reinserted into the first access port and adjacent to the proximally protruding length of cutting element, is extended through the hand immediately above the ligament and out of the second access port. The distally protruding portion of the cutting element is then fed into the distal end of the hollow needle in place within the hand and extended through its length so as to

emerge from the proximal end of the needle after which the needle is retracted from the hand. The routing of the cutting element about the ligament is thereby complete leaving the cutting element in position for the transection. Alternatively, one end of the cutting element may be initially introduced into the distal end of the needle and extended there through. After retraction of the needle and reinsertion into and through the hand above the ligament, the second end of the cutting element is introduced into the distal end of the needle and fed there through. Retraction of the needle leaves the cutting element in place for the transection. As a further alternative, the needle may be reinserted into the hand via the second access port.

[0017] The physical characteristics of the cutting element are selected to facilitate a kerf-less cut through the ligament. The small diameter and high tensile strength of the cutting element provides for the transection of the ligament by the manipulation of the ends of the cutting element. Unequal forces can alternatingly be applied to the two ends of the cutting element to induce a reciprocating cutting action. Alternatively, one end can be pulled with greater force than the other element so as to pull the cutting element in a single direction as it cuts through the ligament. As a further alternative, both ends can be pulled simultaneously with equal force to simply pull the cutting element through the ligament. The substantially smooth, none abrasive surface of the cutting element causes a knife-like cut to be achieved without the formation of a kerf and thus without an attendant deposition of detached material in and about the surgical site. Reciprocation may preferably be achieved with the use of a power tool, by which the two ends of the cutting element are alternating pulled. A stiffened section one or both ends of the cutting element facilitates the introduction of the cutting element into the hollow introducer needle.

[0018] The very small cross-section of the routing tool, whether it takes the form of the hollow introducer needle or the hooked retrieval needle, and of the cutting element, as well as minimally invasive method by which such hardware is introduced and positioned within the hand greatly reduces the risk of injury to the median nerve as well as to the smaller nerves that branch out therefrom. Additionally, the fact that the cutting element is positioned via only two tiny punctures and that the transection is performed via only one of those punctures, recovery time is minimal and scaring is essentially negligible.

[0019] The disclosed method can additionally be modified in order to further simplify the surgical procedure. For example the sequence of steps can altered in the routing of the cutting element about the ligament such that the routing tool is first extended across the top of the ligament before the tool is subsequently extended through the carpal tunnel for the routing of the cutting element about the ligament. Additionally, a rigid alignment tool may be attached to the second end of the cutting element to facilitate engagement of the cutting element by the hooked retrieval needle configuration of the routing tool component at a location completely within the hand and thus much closer to the distal edge of the ligament in order to minimize the transection of any tissue adjacent to the ligament. A retrieval needle may further be marked so as to allow the rotational orientation of the hooking element to be ascertained while within the hand and thereby enhance the ability to engage the cutting element. Additionally, a protective sleeve about a portion of the cutting element may be employed to protect tissue located between the proximal entry port and the ligament. Both ends of the cutting element may be caused to extend through a single sleeve or each end may be caused to extend about its own protective sleeve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020]

FIG. 1 is a cross-sectional view of the carpal tunnel area of the hand;

FIG. 2 is a perspective view of a preferred embodiment of the routing tool component not according to the present invention in the form of a hooked retrieval needle;

FIG. 3 is a perspective view of a preferred embodiment of the cutting element not according to the present invention;

FIGS. 4A-H are cross-sectional views of the hand with a revealed transverse carpal ligament illustrating a preferred sequence of steps for practicing an exemplary method not according to the present invention using a hooked retrieval needle as the routing tool component;

FIGS. 5A-C are cross-sectional views of the hand and the transverse carpal ligament illustrating alternative preferred steps for practicing an exemplary method not according to the present invention;

FIGS. 6A and B are cross-sectional views of the hand and the transverse carpal ligament illustrating an alternative exemplary method not according to the invention in which protective tubes are used;

FIGS. 7A and 7B are greatly enlarged cross-sectional views of an alternative hooked retrieval needle not according to the present invention;

FIG. 8 is a perspective view of a preferred embodiment of the routing tool component of the system according to the present invention in the form of a hollow introducer needle;

FIG. 9 is a perspective view of a preferred embodiment of the cutting element of the present invention;

FIGS. 10A-J are cross-sectional views of the hand with a revealed transverse carpal ligament illustrating a preferred sequence of steps for practicing an exemplary method of use of the system according to the present invention using a hooked retrieval needle as a further routing tool component;

FIG. 11 is a perspective view of a power tool for reciprocating the cutting element once in position

about the target ligament; and

FIG. 12 illustrates the power tool being used to reciprocate the cutting element in place about the ligament.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0021] The present disclosure provides for the minimally invasive transection of tissue and obviates the need for scalpels, saws or endoscopes. The present disclosure is especially applicable for the transection of ligaments and most particularly, for the release of the transverse carpal ligament in the treatment of carpal tunnel syndrome.

[0022] Fig. 1 is a cross-sectional view of the carpal tunnel area of the hand 10. The carpal tunnel 12 is the area of the wrist and palm of the hand 10 formed by a U-shaped cluster of bones 14 that form a hard floor and two walls of the tunnel. The roof of the tunnel is formed by the transverse carpal ligament 16 which attaches to the wrist bones. Within the confines of the tunnel is the median nerve 18 and the flexor tendons 20 of the thumb and fingers. Carpal tunnel syndrome is caused by a compression of the median nerve by either a decrease in the size of the tunnel or an increase in the size of its contents. Such pressure may be relieved by a release of the ligament such as by a transection thereof.

[0023] Fig. 2 is perspective view of a preferred embodiment of the routing tool of the present disclosure wherein such tool takes the form of a hooked retrieval needle 22. The tool generally includes a thin, rigid and elongated distal section 24 and a handle 26 at its proximal end. The distal section has hooking element 28 disposed near its distal end 30. The hooking element is preferably defined by a void formed within the outer diameter of the elongated distal section of the retrieval tool so as to present a substantially smooth outer surface and thereby minimize the potential for trauma as the tool is extended into or retracted from tissue. The distal end may have a sharp tip 29 as is shown in the illustrated embodiment. Alternatively, the tip may have a more blunted configuration. The hooking element is spaced slightly back (reference numeral 30) from the distal end. A marking 32 on the handle may be included demarking the rotational position of the hook-like feature near the tool's distal end. The length of the distal section is selected to be greater than the width of the transverse carpal ligament. Its diameter is selected to be no greater than about 1 mm.

[0024] Fig. 3 is a perspective view of the cutting element 34 of the present disclosure with the optional locator tool 36 attached thereto. The cutting element has a flexible, small diameter, thread-like structure with a high tensile strength and a smooth surface, preferably with an average surface roughness no greater than 50 micrometers . The cutting element may comprise a monofilament or a plurality of braided or otherwise joined fibers or strands wherein each strand has a smooth surface so as to present a relatively smooth, none-abrasive surface. Its physical characteristics include a bend radius of less than half the thickness of the ligament and preferably a zero bend radius, a diameter of less than about 1.0 mm, and a breaking strength of over 0,907 Kg (2 lbs). The cutting element may comprise fiber or yarn formed of cotton, silk, glass fiber, carbon fiber, various plastic fibers or metal. More particularly, textile fiber, synthetic fiber, mineral fiber, polymer fiber, microfibers may be used. The optional locator tool includes a rigid distal end 38 of a diameter sufficiently small to be extended into the access port and to be captured within the hooking element 28 of the retrieval tool 22. A handle 40 is disposed near its proximal end to enable the tool to be grasped and manipulated.

[0025] Figs. 4A-4H illustrate a method of practicing the present disclosure. After anesthetizing the area of the hand 10 near and about the transverse carpal ligament 16, the distal end 30 of the retrieval needle 22 is brought into contact with the hand just proximal to the proximal edge of the target ligament as is shown in Fig. 4A. The ligament is visible in the Figures for purposes of clarity only as no incision is made throughout the entire procedure to in any way expose the ligament to view. Additionally, an imaging device, such as an ultrasound device, such as is commonly used for a variety of imaging applications, is used to visualize the position of the retrieval needle relative to the ligament but is not shown so as not to obscure the surgical site again for purposes of clarity. It is preferable to enter the hand at a position about 30mm proximal of the proximal edge of the transverse carpal ligament as the carpal tunnel can then be entered at a shallower angle obviating the need to adjust the angel of the needle after the tunnel has been reached and thereby minimizing trauma to tissue in addition to allowing the retrieval needle to be more easily imaged.

[0026] In Fig. 4B, the retrieval needle has been advanced into the hand via entry port 42, through the carpal tunnel just under the ligament and out through exit port 44. The entry and exit ports may be formed by the direct extension of the retrieval needle through the skin in the event the retrieval needle 22 is selected to have a sharp distal tip 29. In the event a retrieval tool is used with a blunt tip, a sharp instrument is necessary for forming the access ports and guide the retrieval tool into the hand. The Figure additionally shows the cutting element 34 having been engaged in the hooking element 28 near the tool's distal end. In this particular embodiment, the cutting element is devoid of a locator tool attached to its distal.

[0027] Once the cutting element 34 is engaged, the retrieval needle 22 is retracted from the hand so as to draw a loop 46 of the cutting element into the hand via port 44, through the carpal tunnel and out of entry port 42 as is shown in Fig. 4C. The loop is then disengaged from the retrieval needle and while one end of the cutting element 34a is restrained, the loop is pulled so as to draw the opposite end 34b of the cutting element free of the

hand as is shown in Fig. 4D.

[0028] Fig. 4E illustrates the subsequent step of the method wherein the retrieval needle 22 is readvanced into the hand via access port 42, is guided across the top surface of ligament 16 to remerge from the hand via access port 44. The section of cutting element 34 extending from under the ligament is engaged with the hooking element 28 of the retrieval needle.

[0029] Once the cutting element 34 is again engaged, the retrieval needle 22 is retracted from the hand so as to draw a loop 48 of the cutting element into the hand via port 44, through the carpal tunnel and out of entry port 42 as is shown in Fig. 4F. The loop is then disengaged from the retrieval needle and while end 34b of the cutting element is restrained, the loop is pulled so as to draw the end 34a of the cutting element free of the hand as is shown in Fig. 4G. The cutting element is thereby in position about ligament 16 for subsequent manipulation to effect the transection. As is shown in Fig. 4H, the ends 34a, 34b of the cutting element may simply be grasped by the user, may be wound around the hands or fingers of the user for a firmer grip or alternatively, may be fitted with handles to provide for maximum grip and control. Unequal forces can alternatingly be applied to the two ends of the cutting element to induce a reciprocating cutting action either by hand or with the use of an appropriately configured power tool. Alternatively, one end can be pulled with greater force than the other element so as to pull the cutting element in a single direction as it cuts through the ligament. As a further alternative, both ends can be pulled simultaneously with equal force to simply pull the cutting element through the ligament. When transection has been achieved, the cutting element is simply withdrawn through access port 42. Application of a small bandage over each of the access ports 42, 44 completes the procedure.

[0030] In an alternative embodiment, and as a modification to the step shown in Fig. 4C, the retrieval needle 22 is not completely withdrawn from access port 42 as illustrated in Fig. 5A. The needle is retracted just enough to expose the hooking element 28 and allow the loop 46 of the cutting element 22 to be disengaged and withdrawn, while most of the distal end 30 remains below the skin. As a result, it is more likely that the needle will follow the same pathway to the ligament 16 before traversing its top surface resulting in less trauma and disruption to intervening tissue both while advancing the needle as well as at the completion of the transection step.

[0031] In another alternative embodiment, and as a modification of the step shown in Fig. 4E, the retrieval needle 22 is not extended through port 44 to engage cutting element 34 as is illustrated in Fig. 5B. Rather the cutting element is engaged within the hand, preferably as close to possible to the distal edge of the transverse carpal ligament 16. The needle is shown with its hooking element rotated toward the viewer. The marking 32 on the handle 26 allows the user to ascertain the rotational orientation of the hooking element without a direct view of the distal end of the retrieval needle. By engaging the cutting element 34 closer to the distal edge of the ligament before drawing it across the top surface of the ligament, less extraneous tissue is apt to be captured between the cutting element and the ligament and thus less trauma thereto will be caused during the transection of the ligament.

[0032] As a further alternative to the preferred embodiment shown in Fig. 5B, Fig. 5C illustrates the step using the cutting element 34 having the locator tool 40 attached thereto. Once the distal end 30 of the tool is in position such that the hooking element is located just distal of the distal edge of the transverse carpal ligament as confirmed by the ultrasound image, the cutting element 34 is pulled from the end 34b projecting from access port 42 so as to draw its opposite end 34a and the locator tool that is attached thereto into access port 44. Once the locator tool is extended to the approximate depth that is illustrated, the ability to more readily engage the retrieval needle is enhanced by virtue of the locator tool's visibility under ultrasound imaging and by virtue of the tactile feedback that is provided when contact is made between the rigid distal section 24 of the retrieval needle and the rigid distal end 38 of the locator tool. Once engagement with the hooking element 28 of the retrieval needle is confirmed, the locator tool is withdrawn from access port 44, leaving the cutting element in place within the hooking element. Subsequent retraction of the retrieval needle causes a loop of the cutting element to be drawn through the pathway above the ligament and out of access port 42. Severing the cutting element from the locator tool allows the free end 34a of the cutting element to be drawn through the hand and out of the access port to complete the routing of the cutting element about the target ligament.

[0033] In the event a cutting element 34 is selected that has a larger than zero bend radius, it may be desirable to first introduce a zero bend radius pilot thread into the hand and position it about the ligament in the manner as was described above with regard to placement of the actual cutting element. Once such pilot thread is in place, one end is attached directly to one end of the cutting element and simply pulled through so as to replace the pilot thread with the cutting element. Such approach allows the size of the access ports to be minimized that would otherwise have to be enlarged in order to accommodate the larger loops 46, 48 that are formed by a cutting element having a non-zero bend radius.

[0034] A further alternative method of practicing the present disclosure includes the use of protective tube or tubes 50 that are positioned about the cutting element at access point 42 as is illustrated in Figs. 6A and B. Both ends of the cutting element may be passed through a single tube (Fig. 6A) or each end may be passed through its own tube (Fig. 6B). The tube or tubes serve to protect the surrounding tissue from injury as tension is applied to the cutting element and it is drawn or reciprocated to effect the transection. The tubes are especially effective

when the cutting element undergoes some curvature in and about access point 42. The thin-walled tubing is selected to be flexible but resistant to being cut by the cutting element.

[0035] In another alternative preferred embodiment, a modified retrieval tool 52 is configured for capture within a hypodermic needle 54 as is shown in Figs. 7A and 7B. The hypodermic needle is initially used to form access port 42, to inject anesthetic and/or a liquid, such as saline solution, to inflate the surgical site so as to separate the various tissues and components to provide easier access for routing the cutting element into place. After the injection is complete, the hypodermic needle is extended out of the body to form access port 44. The specially configured blunt tipped retrieval tool is inserted into the hypodermic needle and locked into place (Fig. 7B) via locking mechanism 56. Such locking mechanism may take any of various forms including the interference fit that is created by the slightly wavy configuration of the shank 58 that is shown in the Figure. After the cutting element is engaged by the hooking element 28 of the retrieval tool, the hypodermic needle is retracted to draw loop 46 into the hand as is shown in Fig. 4C. The distal section 60 of the retrieval tool 52 may have its outer diameter selected to substantially match the outer diameter of the hypodermic needle to create a smooth transition.

[0036] Fig. 8 is perspective view of an embodiment of routing tool component of the system according to the present invention wherein the tool takes the form of a hollow introducer needle 70. The hollow needle includes a sharp or blunt distal end 72 and has hollow interior extending from its distal end to its proximal end 74. A handle 76 may be disposed about its proximal section to facilitate its manipulation. The length of the section of introducer needle distal to the handle is selected to be greater than the width of the target transverse carpal ligament. Its diameter is selected to be no greater than about 2 mm.

[0037] Fig. 9 is a perspective view of a preferred embodiment of the cutting element 78 of the system according to the present invention. Substantially the entire length 80 of the cutting element has a flexible, small diameter, thread-like structure with a high breaking strength and a smooth surface, preferably with an average surface roughness no greater than 50 micrometers . The cutting element may comprise a monofilament or a plurality of braided, twisted or otherwise joined fibers or strands wherein each strand has a smooth surface so as to present a relatively smooth, non-abrasive surface. Its physical characteristics include a bend radius of less than half the thickness of the ligament and preferably a zero bend radius, a diameter of less than about 1.0 mm, and a breaking strength of over 0,907 Kg (2 lbs). The cutting element may comprise fiber or yarn formed of cotton, silk, glass fiber, carbon fiber, various plastic fibers or metal. More particularly, textile fiber, synthetic fiber, mineral fiber, polymer fiber, microfibers may be used. At least one end of the cutting element has a stiffened section 82 to facilitate the introduction into and the extension through the hollow introducer needle. 70. The stiffened section may be formed by covering the section with relatively stiff tubing, by subjecting a synthetic fiber to heat, by the infusion of for example a resin or by the attachment of for example a suture needle. The stiffened section 82 preferably has a diameter less than the inner diameter of the introducer needle. The enhanced diameter shown in the drawing is for illustration purposes only.

[0038] Figs. 10A-J illustrate an exemplary method of use of the system according to the present invention. After anesthetizing the area of the hand 10 near and about the transverse carpal ligament 16, the distal end 72 of the hollow introducer needle 70 is brought into contact with the hand just proximal to the proximal edge of the target ligament as is shown in Fig. 10A. The ligament is visible in the Figures for purposes of clarity only as no incision is made throughout the entire procedure to in any way expose the ligament to view. Additionally, an imaging device, such as an ultrasound device, such as is commonly used for a variety of imaging applications, is used to visualize the position of the introducer needle relative to the ligament but is not shown so as not to obscure the surgical site again for purposes of clarity. It is preferable to enter the hand at a position about 30mm proximal of the proximal edge of the transverse carpal ligament as the carpal tunnel can then be entered at a shallower angle obviating the need to adjust the angel of the needle after the tunnel has been reached and thereby minimizing trauma to tissue in addition to allowing the introducer needle to be more easily imaged.

[0039] In Fig. 10B, the introducer needle has been advanced into the hand via entry port 42, through the carpal tunnel just under the ligament and out through exit port 44. The entry and exit ports may be formed by the direct extension of the introducer needle through the skin. The Figure additionally shows the cutting element 78 being advanced toward the proximal opening of introducer needle wherein the stiffened section 82 of the cutting element serves to facilitate the threading of the cutting element into the needle's hollow interior.

[0040] Fig. 10C shows the cutting element emerging from the introducer needle's distal end while Fig. 10D illustrates the subsequent retraction of the needle to leave the cutting element in place as is shown in Fig. 10E. As such, a section of cutting element 78 is left projecting from entry port 42 and from access port 44 while its central section extends through the carpal tunnel just below the transverse carpal ligament 16.

[0041] Fig. 10F illustrates the subsequent step of the method wherein the introducer needle has been reintroduced into the hand via entry port 42 immediately adjacent to the placed cutting element 78. The introducer needle has been advanced through the hand immediately above the transverse carpal ligament 16 to reemerge from access port 44. Alternatively, the introducer needle may be reintroduced into the hand via access port 44 to reemerge from port 42.

[0042] Once the introducer needle 70 is again in place, the cutting element 78 is fed into the distal end of the introducer needle, is extended along the needle's hollow interior to project from its proximal end as is shown in Fig. 10H. Subsequent retraction of the introducer needle as per Fig. 10I leaves the cutting element in position about the ligament 16 as is shown in Fig. 10J. The cutting element is thereby in position for subsequent manipulation to effect the transection of the ligament.

[0043] Alternatively, a cutting element having a stiffened section at both ends allows the cutting element to be initially introduced into the distal end of the introducer needle and extended there through. After retraction of the needle and reintroduction into the hand and extension above the ligament to re-emerge from the hand, the second stiffened end of the cutting element can be inserted into the distal end of the needle and extended there through. Subsequent retraction of the needle again leaves the cutting element in position for the transection.

[0044] The cutting element may simply be grasped by the user, may be wound around the hands or fingers of the user for a firmer grip or alternatively, may be fitted with handles to provide for maximum grip and control. Unequal forces can alternatingly be applied to the two ends of the cutting element to induce a reciprocating cutting action either by hand or with the use of an appropriately configured power tool. Alternatively, one end can be pulled with greater force than the other element so as to pull the cutting element in a single direction as it cuts through the ligament. As a further alternative, both ends can be pulled simultaneously with equal force to simply pull the cutting element through the ligament. When transection has been achieved, the cutting element is simply withdrawn through access port 42. Application of a small bandage over each of the access ports 42, 44 completes the procedure.

[0045] Fig. 11 generally illustrates a power tool 90 for reciprocating the ends of the cutting element 78. The power tool may include a hand grip section 92, which may house a battery pack. An electric motor would be housed in section 94, rotation of which is mechanically converted to a reciprocating effect. In the embodiment shown, reciprocation is achieved by the rotation of a crankshaft wherein a pin 98 extends from a rotatable disc on each side of the device wherein the pins are diametrically opposed relative one another and to which the ends of the cutting element 78 are attached. Converting the rotation of a longitudinally positioned electric motor to a transversely disposed crankshaft can be achieved in any of various well known ways including for example geared, cammed or desmodromic mechanisms among many others.

[0046] Fig. 12 illustrates the power tool 90 being used to reciprocate the cutting element 78 in place about the transverse carpal ligament. A protective sleeve 50 may be fitted so as to maintain the two ends of the cutting element in alignment with one another and minimize trauma to the surrounding tissue.

[0047] While particular forms of the invention have been described and illustrated, it will also be apparent to those skilled in the art that various modifications can be made without departing from the scope of the invention defined by the claims. Additionally, the method and appropriately dimensioned retrieval tool can be used to transect other tissue so as to perform for example, but no limited to, trigger finger release surgery, tarsal tunnel release surgery and plantar fascia release surgery. The apparatus and method can readily be adapted to transect other soft tissue such as for example muscle, tendon, vessels and nerves in humans as well as animals.

Claims

1. A system for transecting soft tissue within a body through at least a first and a second access ports (42) formed in the body, the system comprising:

   a flexible thread-like cutting element (34) having a first end and a second end, the cutting element having a zero bend radius between the first end and the second end, and
   a routing tool (70) having a hollow interior extending from a proximal end to a distal end with an internal diameter sufficient to receive the flexible cutting element, the distal end of the routing tool comprising a sharp tip to penetrate tissue to facilitate its extension into the body adjacent to said soft tissue and to route said thread-like cutting element about said soft tissue to allow both ends of said cutting element (34) to extend from the access ports (42) in said body,
   characterized in that
   at least one of the first end and the second end of the flexible thread-like cutting element (34) has a stiffened section (82); and
   the cutting element (34) has a smooth and non-abrasive surface.

2. The system of claim 1, further comprising an imaging device capable of visualizing said routing tool (70) within said body relative to said soft tissue.

3. The system of claim 2, wherein said imaging device comprises an ultrasound imaging device.

4. The system of claim 1, wherein said cutting element (34) has a diameter less than 1.0 mm.

5. The system of claim 1, wherein said cutting element (34) has a breaking strength of greater than 0,907 Kg (2 lbs).

6. The system of claim 1, wherein said cutting element (34) has a braided or twisted structure or comprises a monofilament.

7. The system of claim 1, further comprising a power tool (90) for alternately reciprocating ends of said cutting element.

8. The system of claim 1, further comprising a hollow sleeve dimensioned to receive both ends of said cutting element and formed of a material selected to allow movement of said cutting element therein without being cut thereby.

9. The system of claim 1, wherein the system comprises an injection needle having the function of injecting liquid through the routing tool and into the body to inflate the surgical site so as to separate the various tissue and components to provide easier access for routing the cutting element (34) into place.

10. The system of claim 1, wherein said system for transecting soft tissue in the body can be used to perform, for example but not limited to, carpal tunnel release surgery, trigger finger release surgery, tarsal tunnel release surgery, and plantar fascia release surgery.

Patentansprüche

1. Ein System zur Durchtrennung von Weichgewebe innerhalb eines Körpers durch mindestens eine erste und eine zweite im Körper gebildete Zugangsöffnung (42), wobei das System folgendes umfasst:

   ein flexibles fadenartiges Schneidelement (34), das ein erstes Ende und ein zweites Ende hat, wobei das Schneideelement einen Biegeradius von Null zwischen dem ersten und dem zweiten Ende hat, und
   ein Führungswerkzeug (70), das einen hohlen Innenraum hat, der sich von einem proximalen Ende bis zu einem distalen Ende erstreckt und der einen Innendurchmesser hat, der ausreicht, um das flexible Schneidelement aufzunehmen, wobei das distale Ende des Führungswerkzeugs eine scharfe Spitze umfasst, um Gewebe durchzudringen, um dessen Ausdehnung in dem Körper in einer an das Weichgewebe angrenzenden Stelle zu ermöglichen und um das fadenartige Schneidelement um das Weichgewebe herum zu führen, um zu ermöglichen, dass beide Enden des Schneidelements (34) sich von den Zugangsöffnungen (42) in dem Körper erstrecken,
   dadurch gekennzeichnet, dass
   mindestens eines von dem ersten Ende und dem zweiten Ende des flexiblen fadenartigen Schneidelements (34) einen versteiften Abschnitt (82) hat; und
   das Schneidelement (34) eine glatte und nicht abreibende Oberfläche hat.

2. Das System des Anspruchs 1, weiterhin umfassend eine Bildgebungsvorrichtung, die das Führungswerkzeug (70) innerhalb des Körpers bezüglich des Weichgewebes sichtbar machen kann.

3. Das System des Anspruchs 2, wobei die Bildgebungsvorrichtung eine auf Ultraschall beruhende Bildgebungsvorrichtung umfasst.

4. Das System des Anspruchs 1, wobei das Schneidelement (34) einen Durchmesser von weniger als 1,0 mm hat.

5. Das System des Anspruchs 1, wobei das Schneidelement (34) eine Bruchfestigkeit von mehr als 0,907 kg (2 lb) hat.

6. Das System des Anspruchs 1, wobei das Schneidelement (34) eine geflochtene oder gedrehte Struktur hat oder ein Monofilament umfasst.

7. Das System des Anspruchs 1, weiterhin umfassend ein Elektrowerkzeug (90) für abwechselnd hin- und hergehende Enden des Schneidelements.

8. Das System des Anspruchs 1, weiterhin umfassend eine hohle Hülse mit Abmessungen zur Aufnahme von beiden Enden des Schneidelements und die aus einem Material besteht, das ausgewählt ist, um eine Bewegung des Schneidelements darin zu ermöglichen, ohne dadurch geschnitten zu werden.

9. Das System des Anspruchs 1, wobei das System eine Injektionsnadel umfasst, deren Funktion ist, Flüssigkeit durch das Führungswerkzeug und in den Körper einzuspritzen, um die chirurgische Stelle aufzublasen, um die verschiedenen Gewebe und Bestandteile zu trennen, um einen einfacheren Zugang zur Führung des Schneidelements (32) in die richtige Position zu bieten.

10. Das System des Anspruchs 1, wobei das System zur Durchtrennung von Weichgewebe in dem Körper verwendet werden kann um zum Beispiel, aber nicht darauf beschränkt, folgendes durchzuführen: chirurgische Karpaltunnelspaltung, chirurgische Ringbandspaltung, chirurgische Tarsaltunnelspaltung und chirurgische Spaltung der Aponeurosis plantaris.

Revendications

1. Un système de coupe transversale de tissu mou dans un corps à travers au moins des ouvertures d'accès première et seconde (42) formées dans le

corps, le système comprenant :

un élément de coupe filiforme souple (34) ayant une première extrémité et une seconde extrémité, l'élément de coupe ayant un rayon de courbure égal à zéro entre la première extrémité et la seconde extrémité, et
un outil d'acheminement (70) ayant un intérieur creux s'étendant d'une extrémité proximale jusqu'à une extrémité distale et ayant un diamètre intérieur suffisant pour recevoir l'élément de coupe souple, l'extrémité distale de l'outil d'acheminement comprenant une pointe acérée pour pénétrer du tissu afin de faciliter son extension dans le corps dans une position adjacente audit tissu mou et afin d'acheminer ledit élément de coupe filiforme autour dudit tissu mou afin de permettre que toutes deux extrémités dudit élément de coupe (34) s'étendent à partir des ouvertures d'accès (42) dans ledit corps,
caractérisé en ce que
au moins une de la première extrémité et la seconde extrémité de l'élément de coupe filiforme souple (34) a une section renforcée (82) ; et
l'élément de coupe (34) a une surface lisse et non abrasive.

2. Le système de la revendication 1, comprenant en outre un dispositif d'imagerie capable de rendre visible ledit outil d'acheminement (70) dans ledit corps par rapport audit tissu mou.

3. Le système de la revendication 2, dans lequel ledit dispositif d'imagerie comprend un dispositif d'imagerie par ultrasons.

4. Le système de la revendication 1, dans lequel ledit élément de coupe (34) a un diamètre inférieur à 1,0 mm.

5. Le système de la revendication 1, dans lequel ledit élément de coupe (34) a une résistance à la rupture supérieure à 0,907 kg (2 lb).

6. Le système de la revendication 1, dans lequel ledit élément de coupe (34) a une structure tressée ou torsadée ou comprend un mono-filament.

7. Le système de la revendication 1, comprenant en outre un outil électrique (90) pour des extrémités dudit élément de coupe qui ont un mouvement alternatif de va-et-vient.

8. Le système de la revendication 1, comprenant en outre un manchon creux dont les dimensions permettent de recevoir toutes deux extrémités dudit élément de coupe et qui est fait en un matériau choisi de manière à permettre le mouvement dudit élément de coupe dans son intérieur sans être coupé par celui-ci.

9. Le système de la revendication 1, dans lequel le système comprend une aiguille d'injection ayant la fonction d'injecter du liquide à travers l'outil d'acheminement et dans le corps afin de gonfler le site chirurgical de manière à séparer les différents tissus et composants afin de fournir un accès plus aisé pour acheminer l'élément de coupe (34) vers la position correcte.

10. Le système de la revendication 1, dans lequel ledit système de coupe transversale de tissu mou dans le corps peut être utilisé pour effectuer, par exemple, mais sans s'y restreindre, de la chirurgie de libération du canal carpien, de la chirurgie de libération du doigt à ressaut, de la chirurgie de libération du canal tarsien et de la chirurgie de libération du fascia plantaire.

FIG. 1

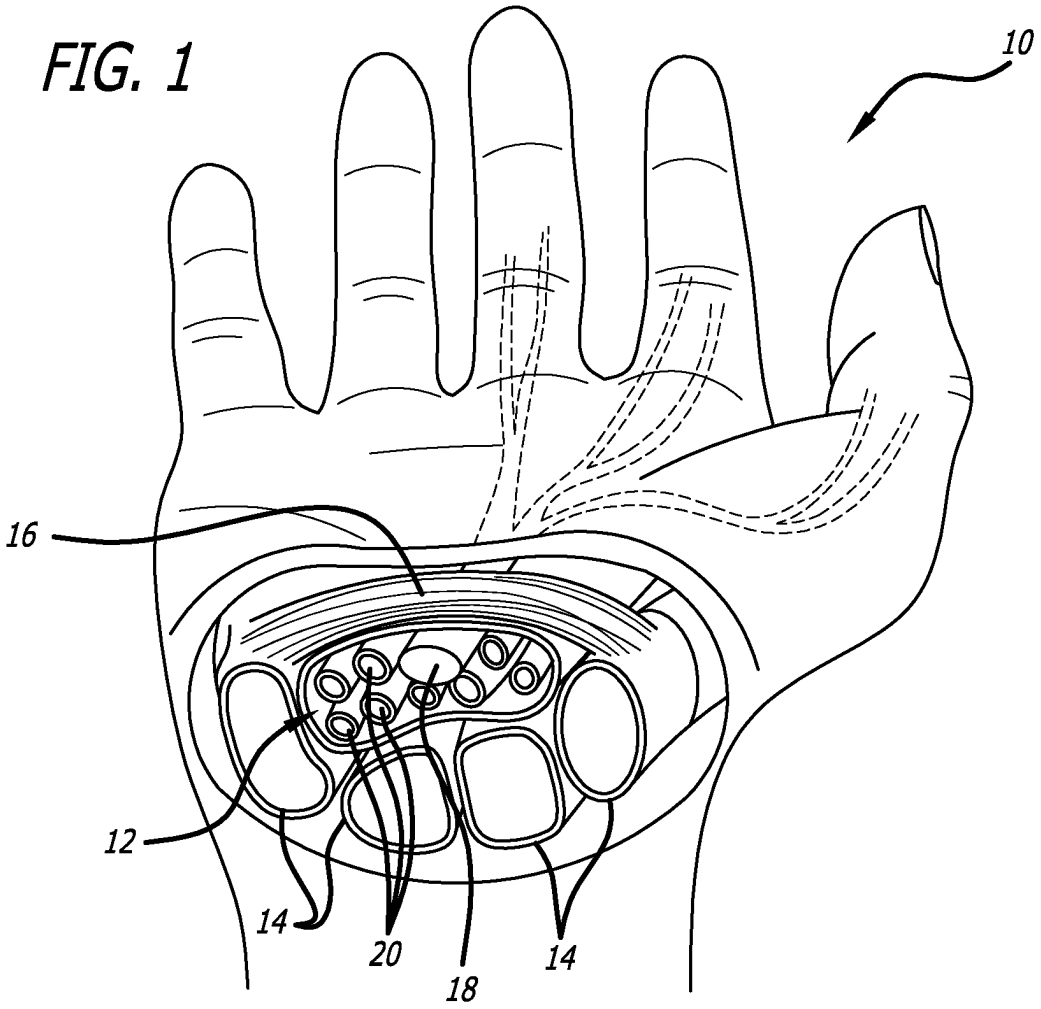


FIG. 2

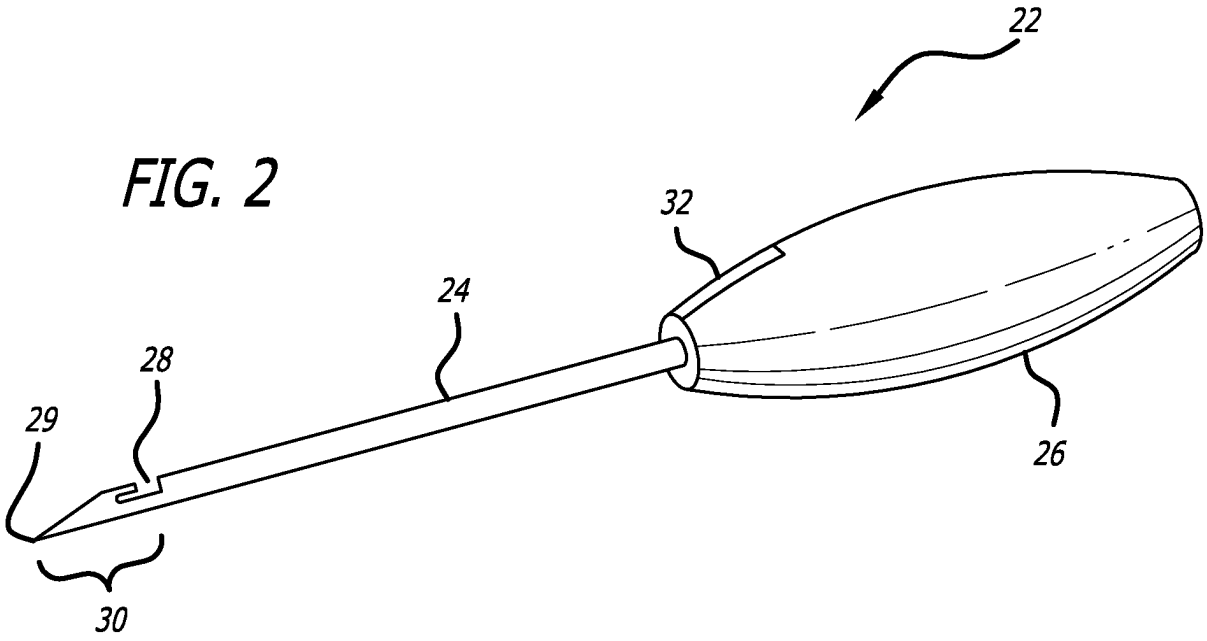
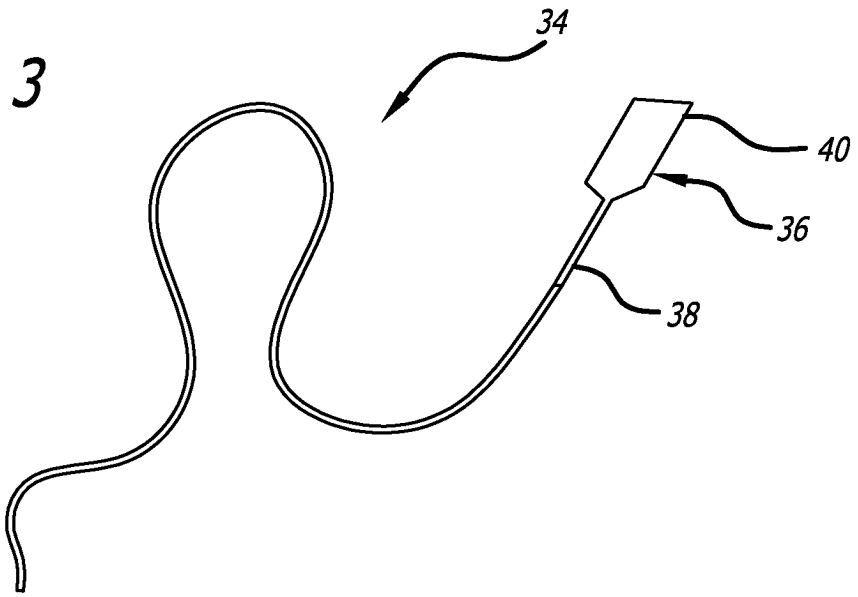


FIG. 3



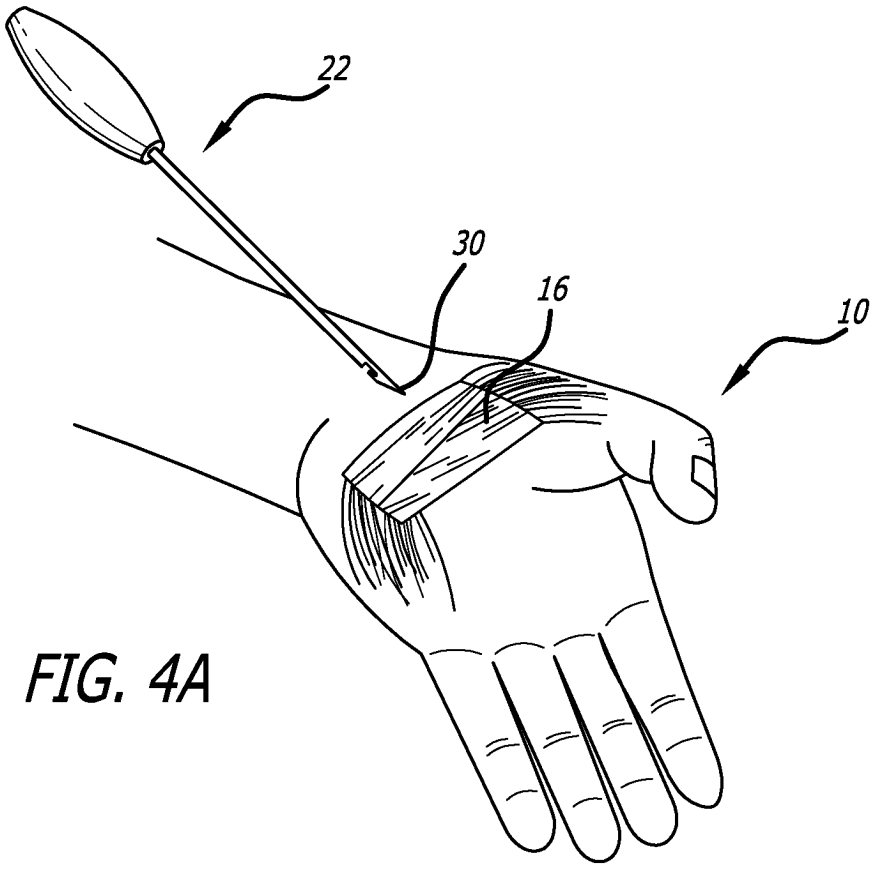


FIG. 4A

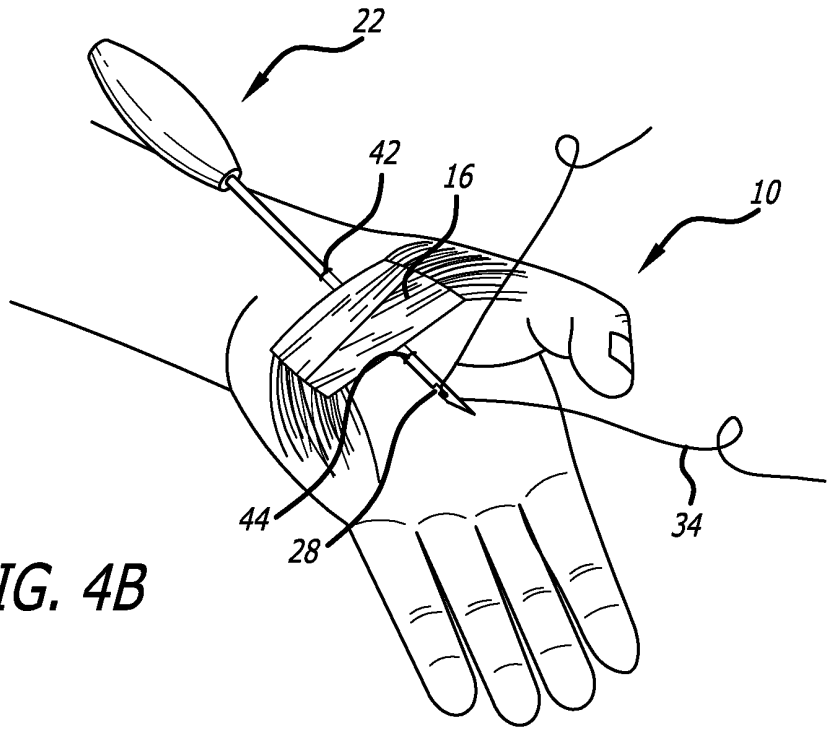


FIG. 4B

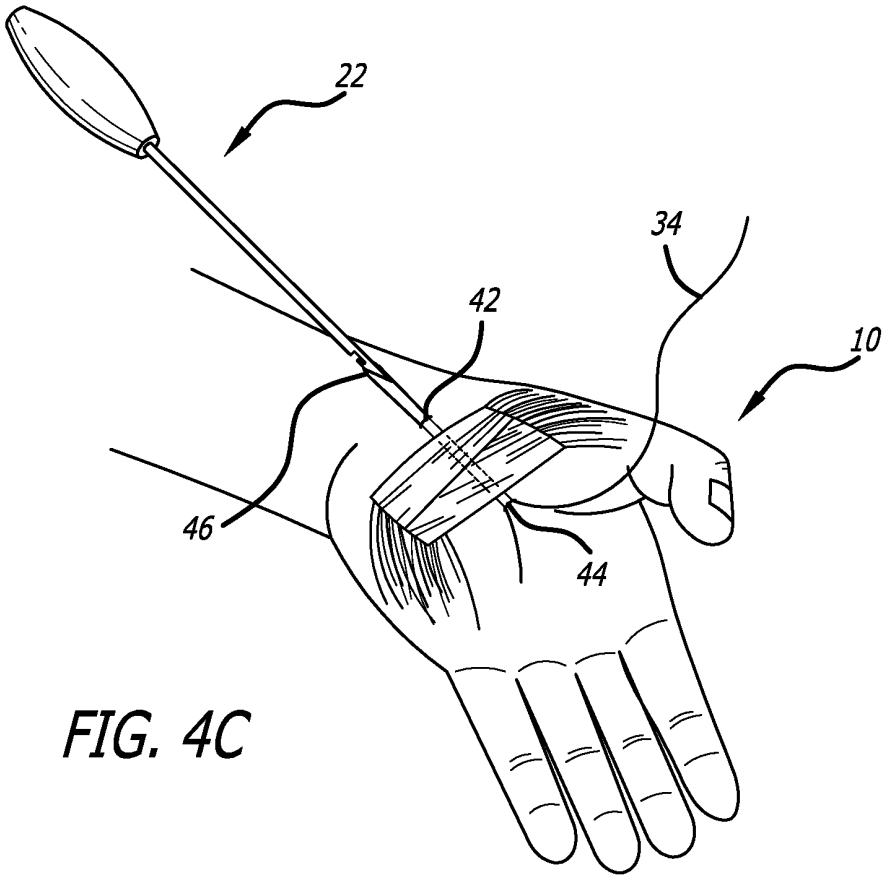


FIG. 4C

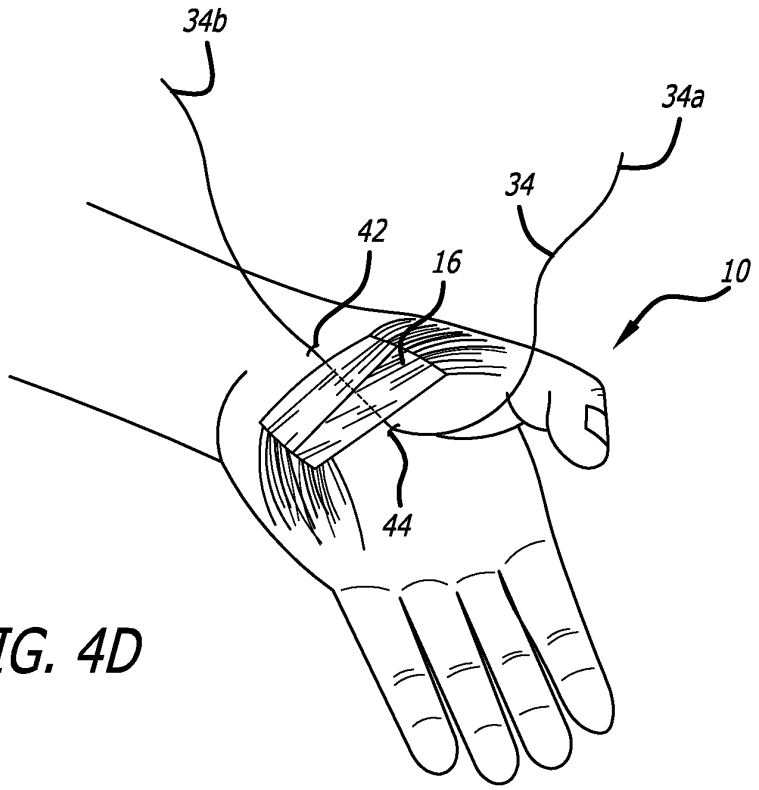


FIG. 4D

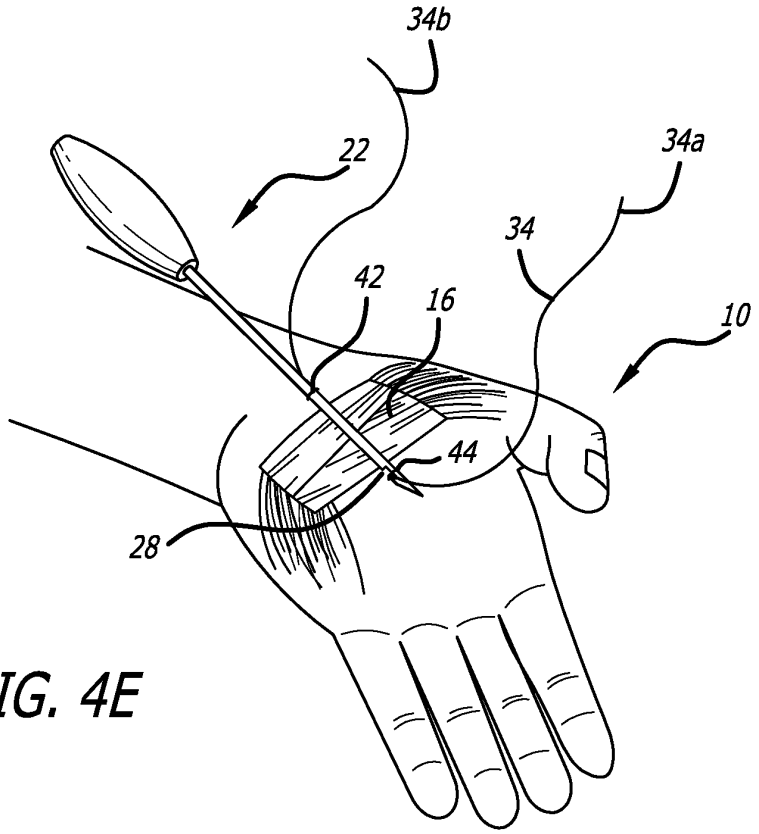


FIG. 4E

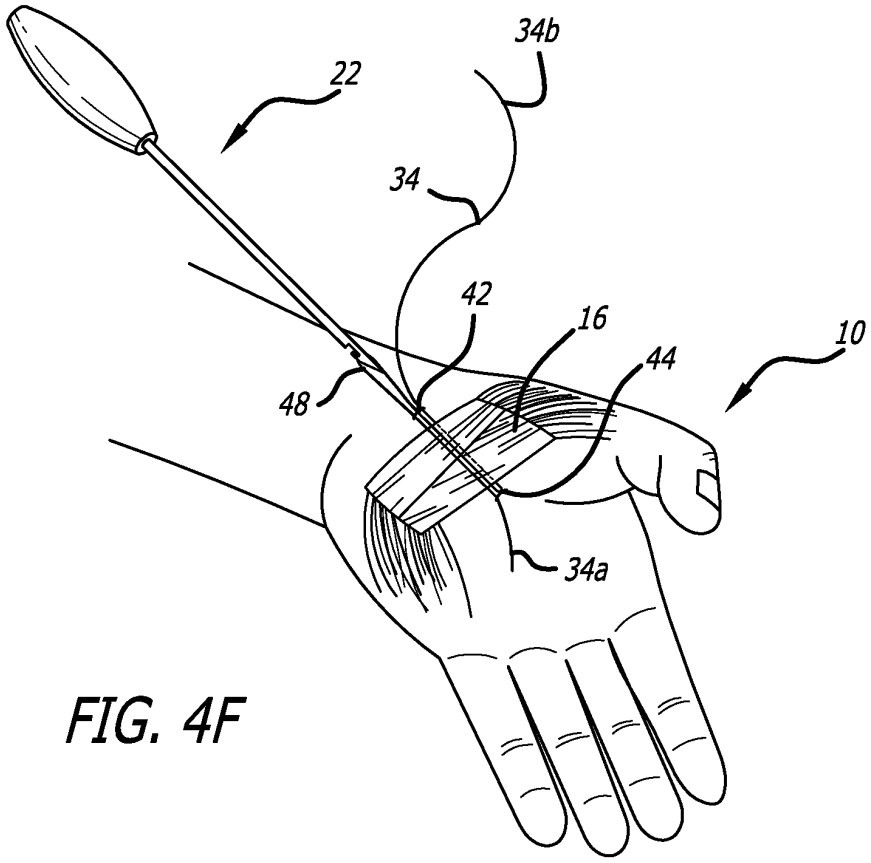


FIG. 4F

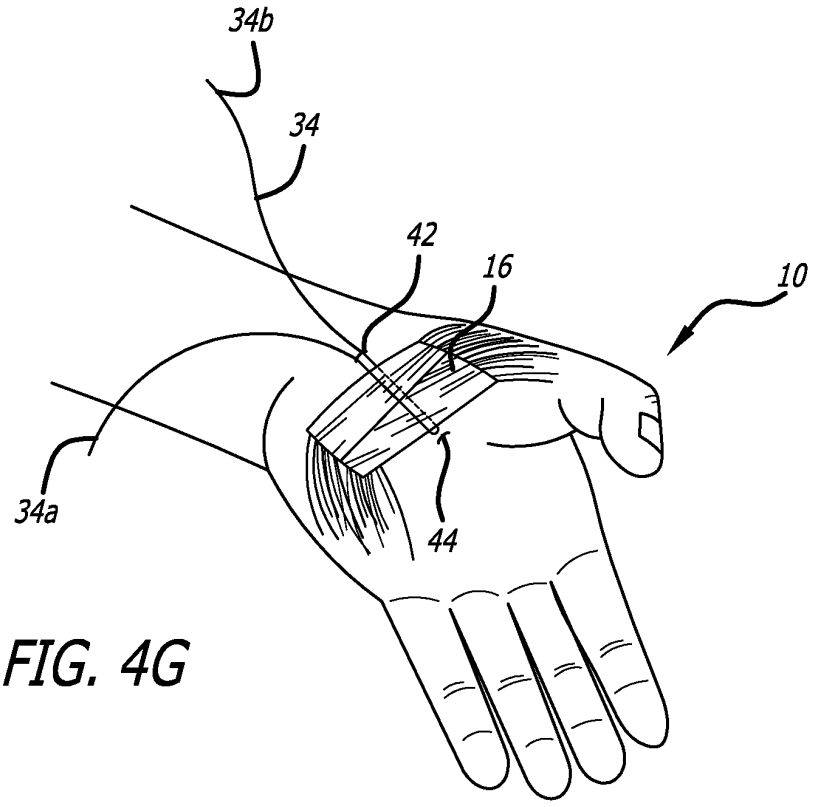


FIG. 4G

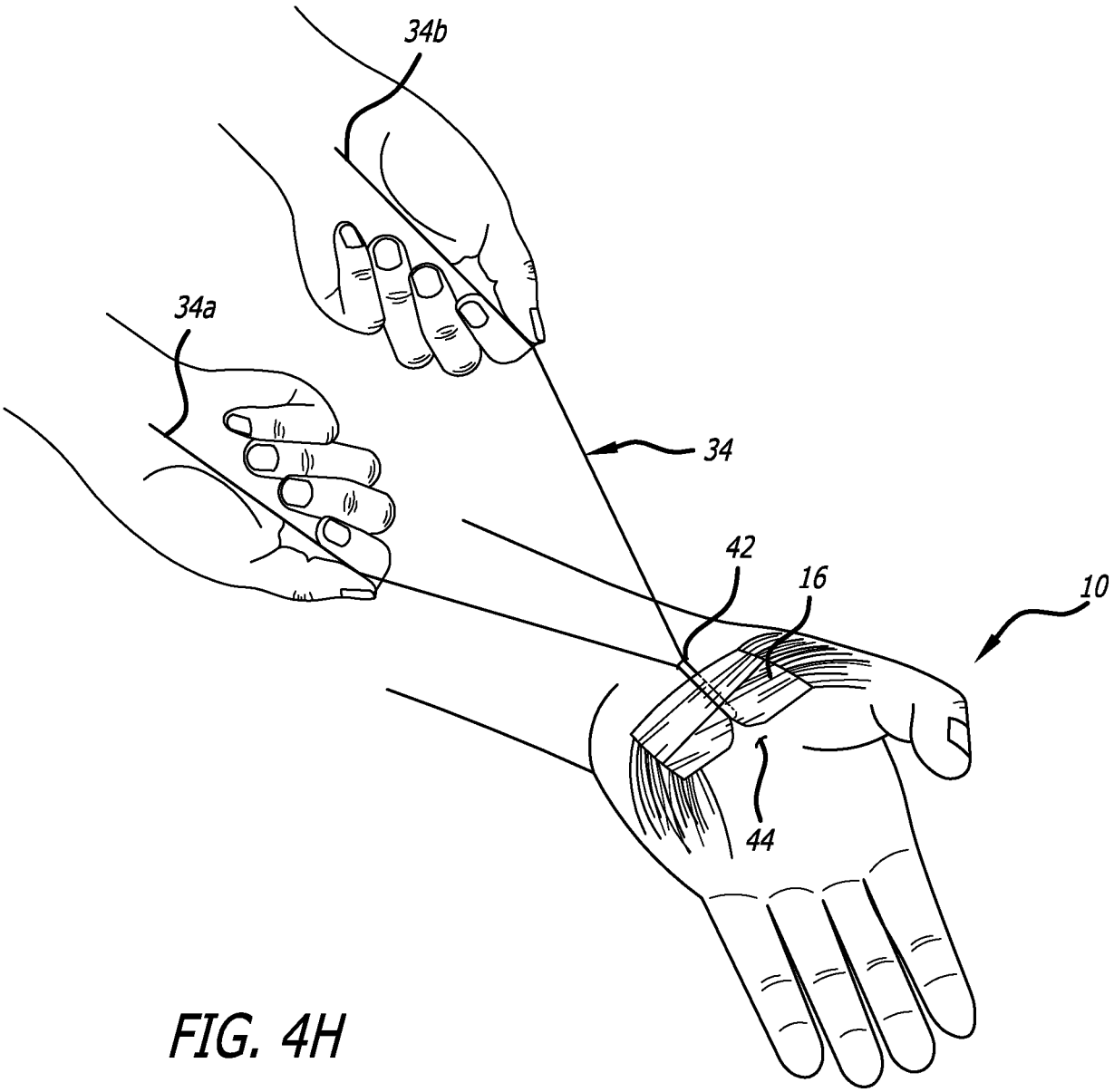


FIG. 4H

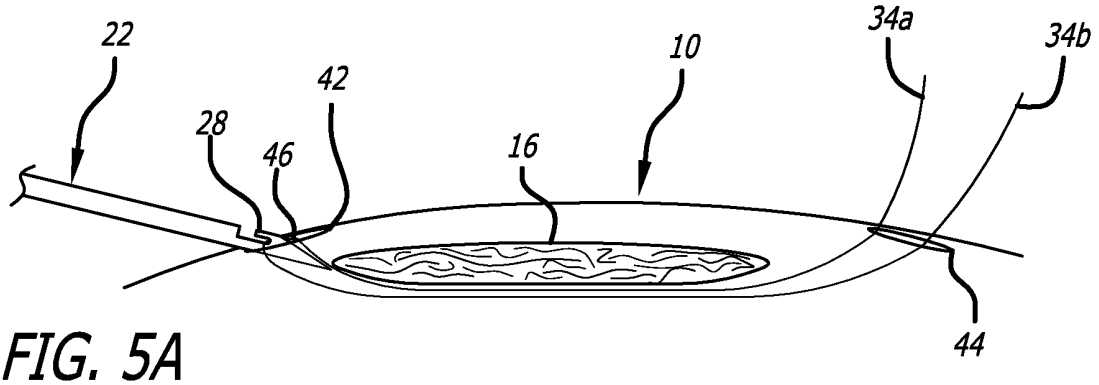


FIG. 5A

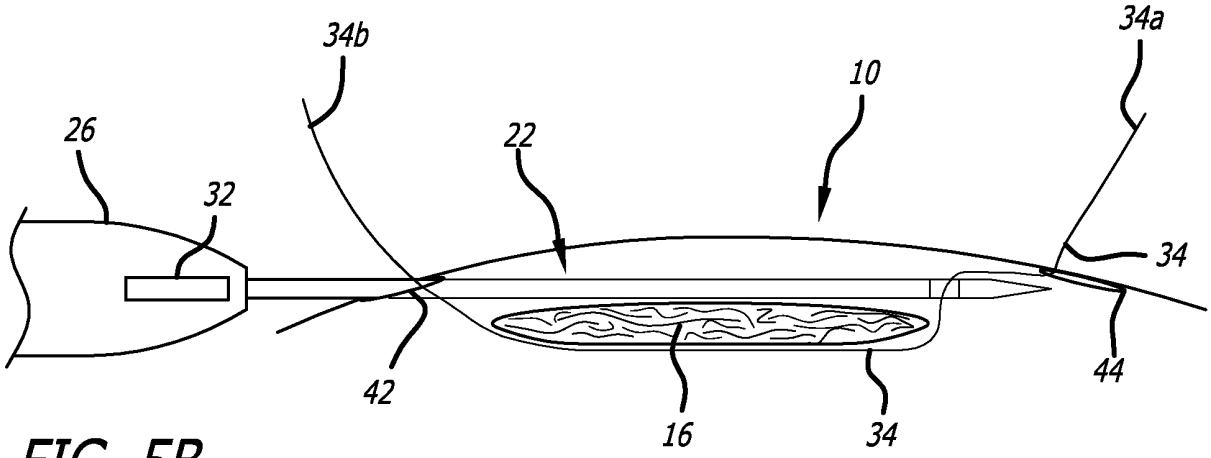


FIG. 5B

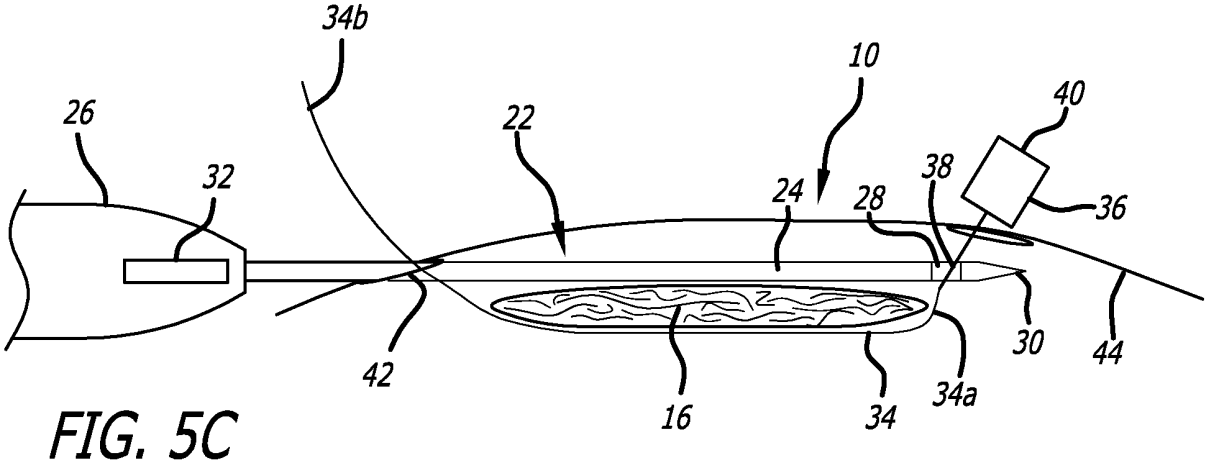


FIG. 5C

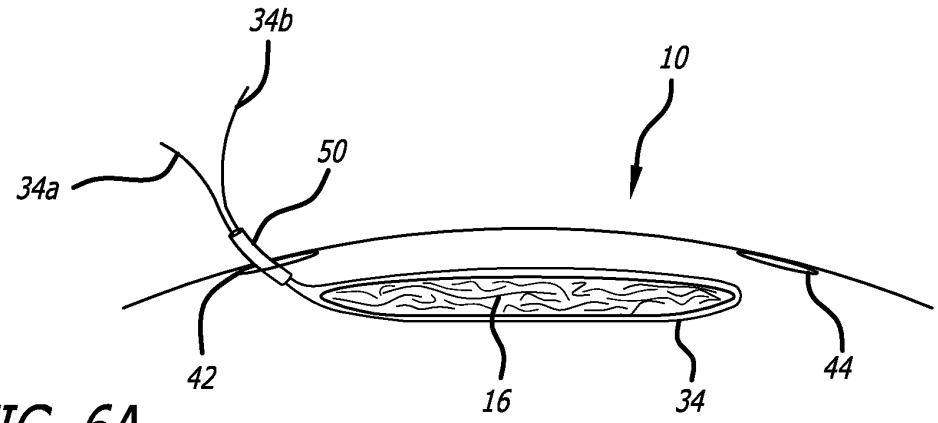


FIG. 6A

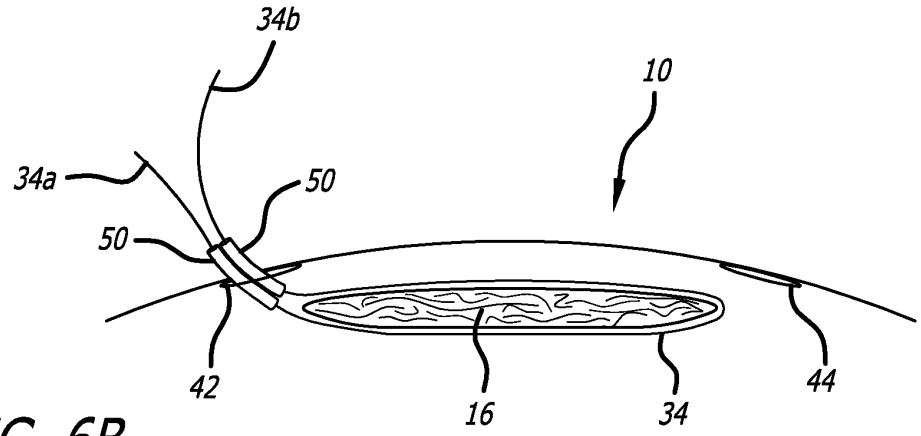


FIG. 6B

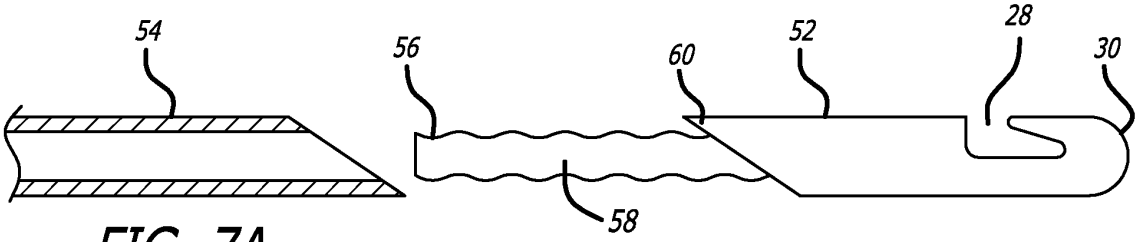


FIG. 7A

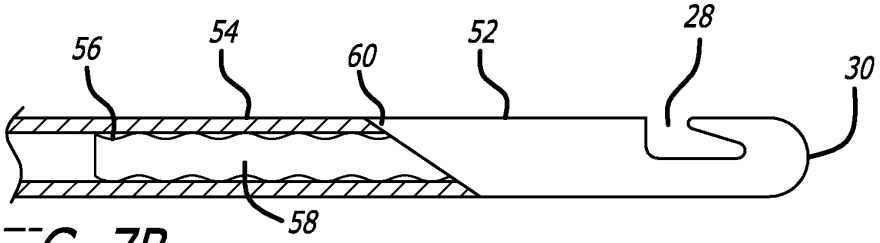


FIG. 7B

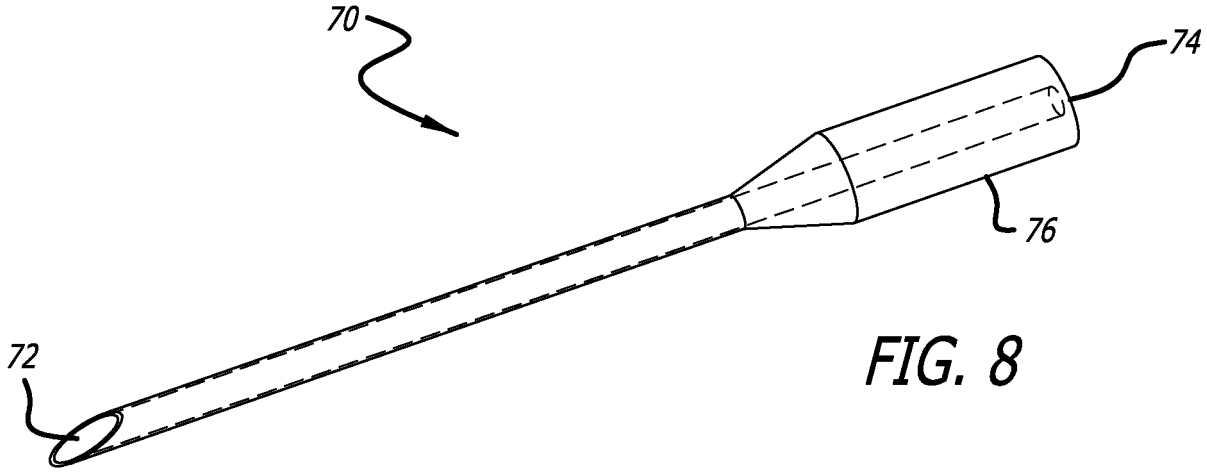


FIG. 8

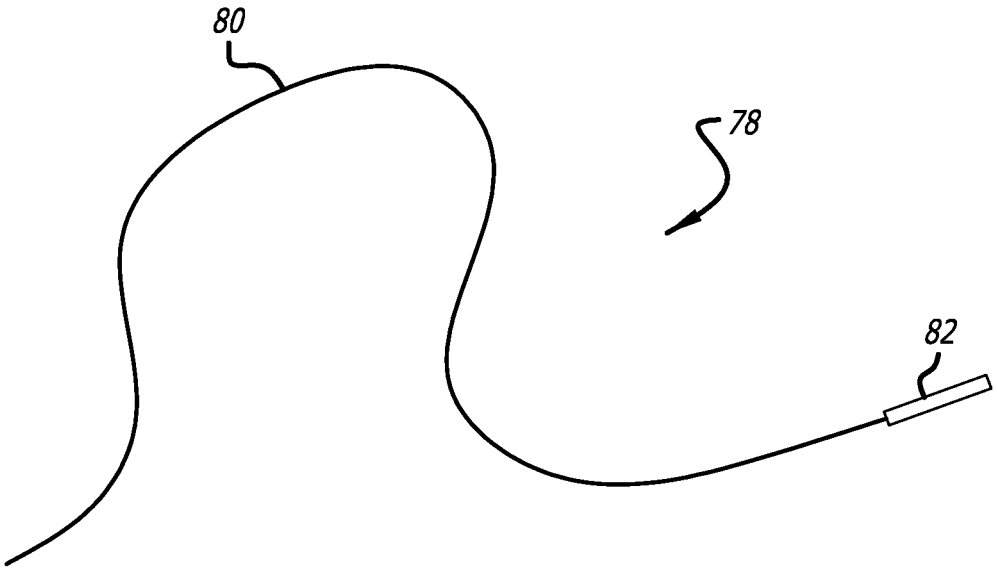


FIG. 9

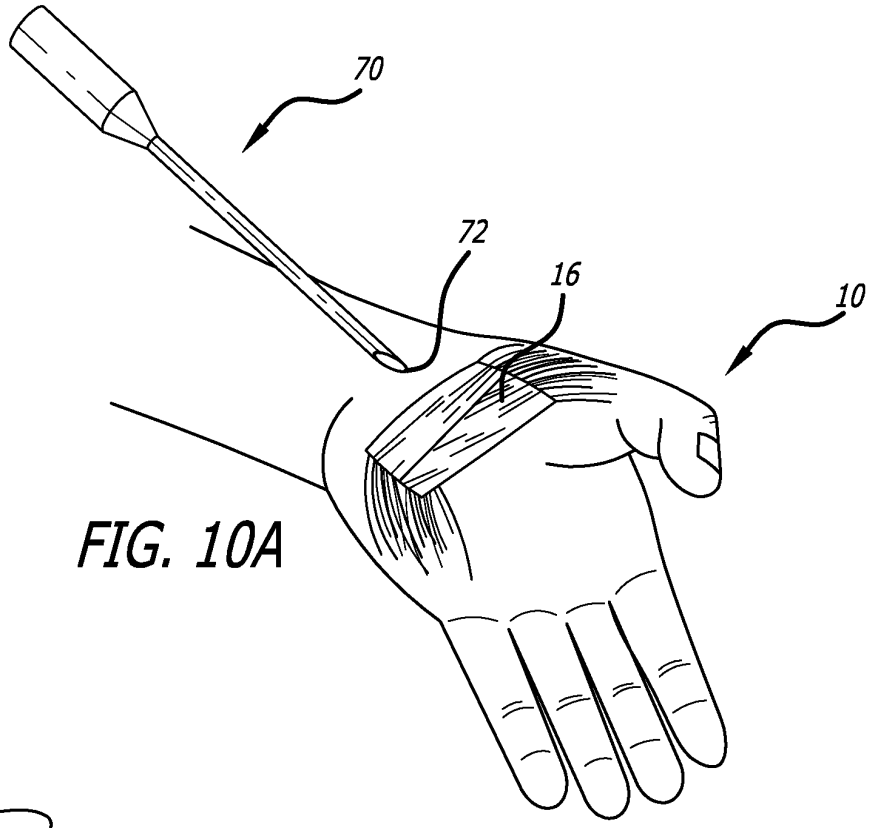


FIG. 10A

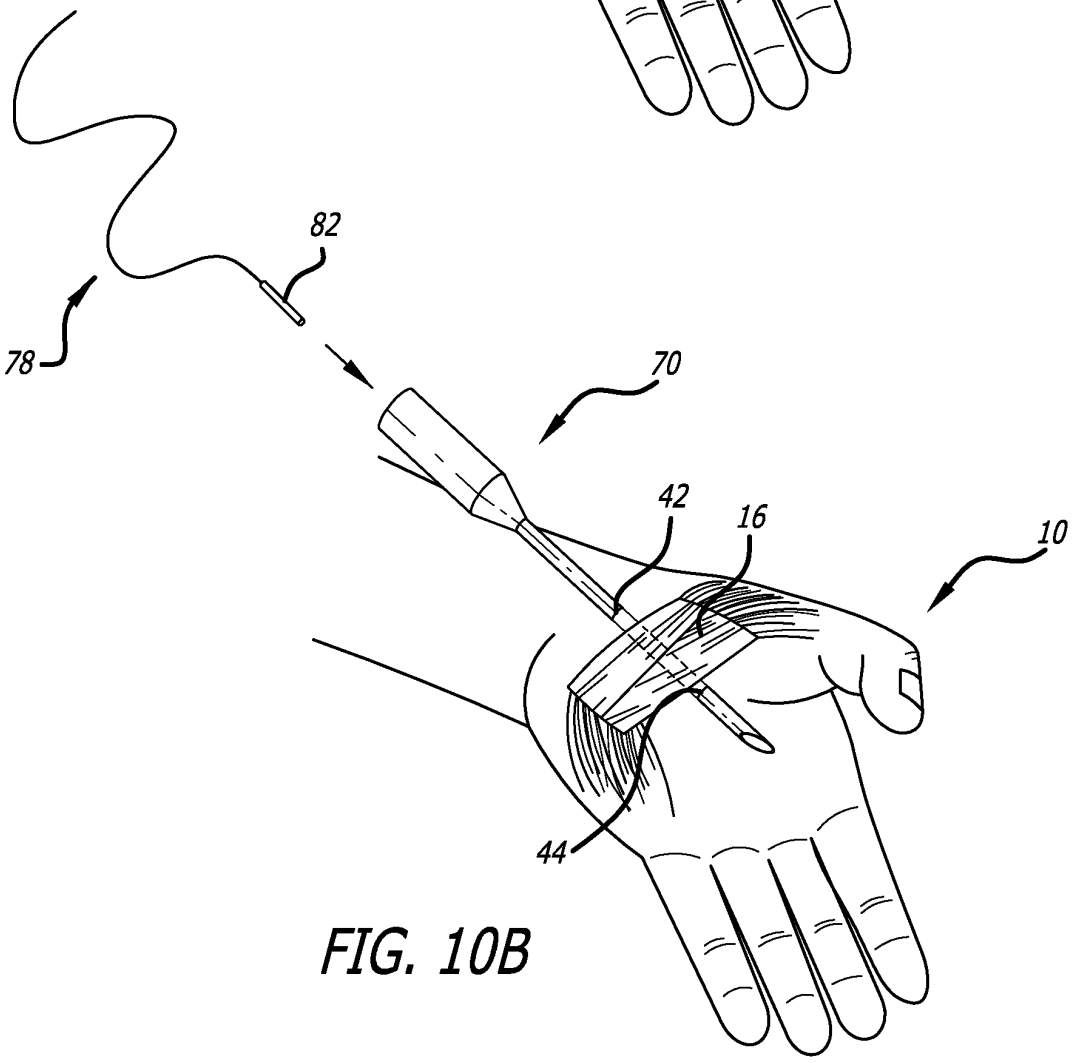


FIG. 10B

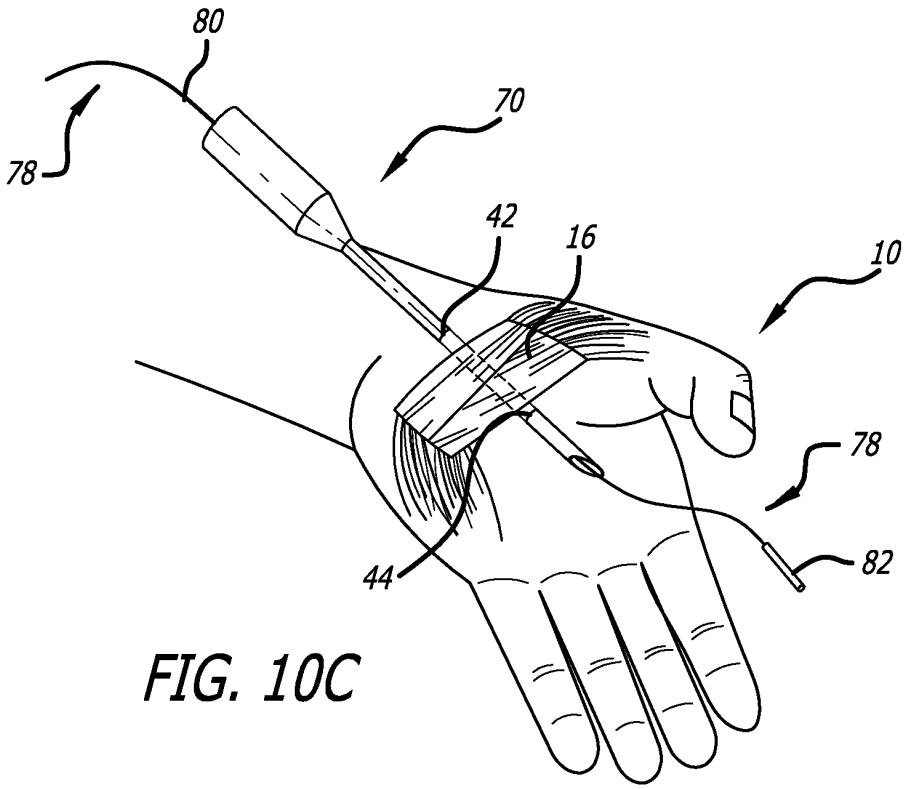


FIG. 10C

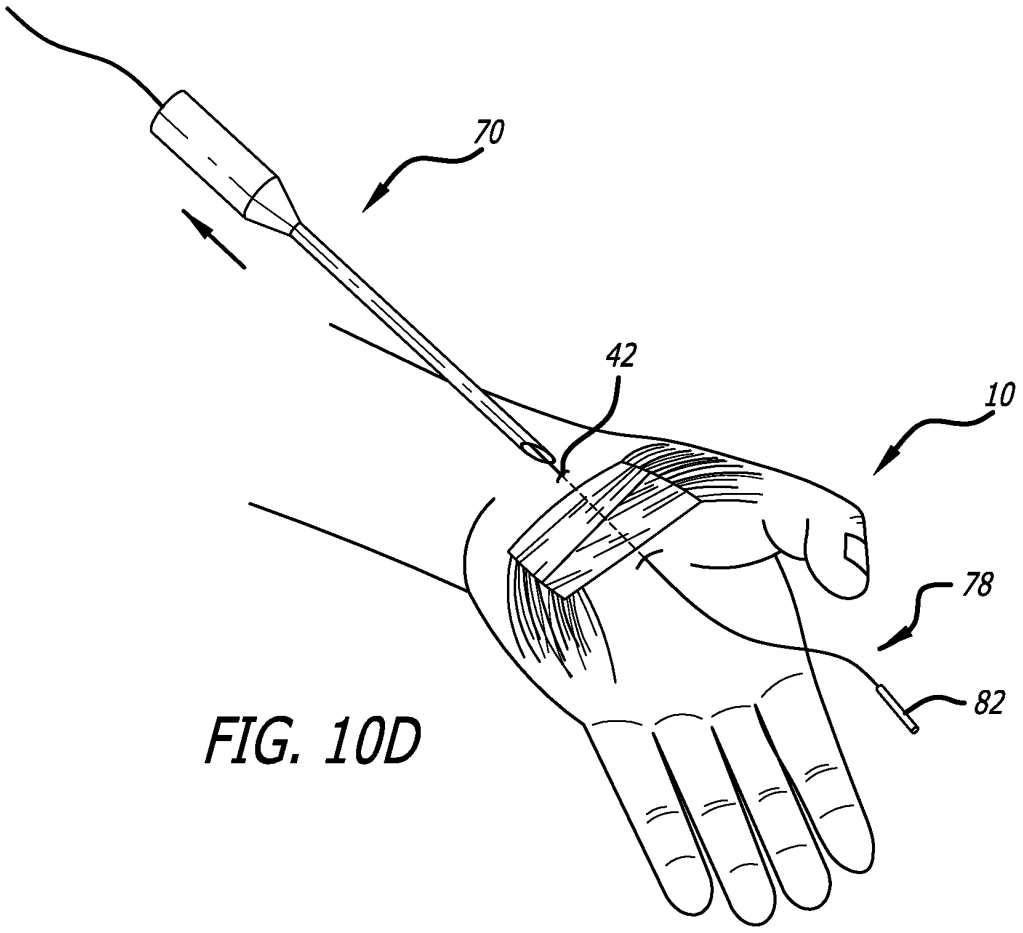


FIG. 10D

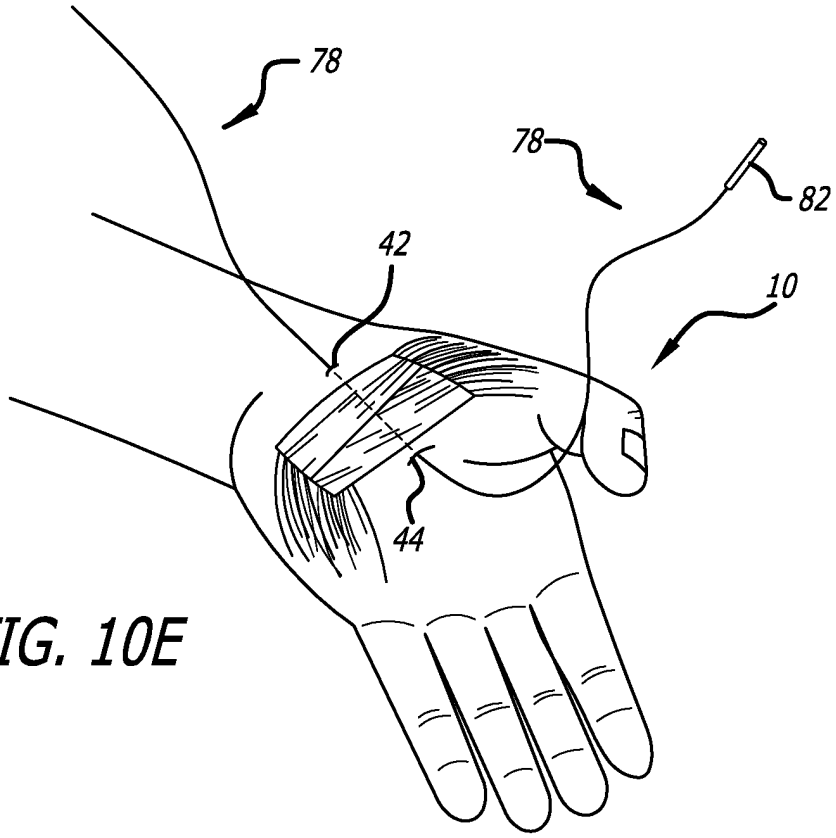


FIG. 10E

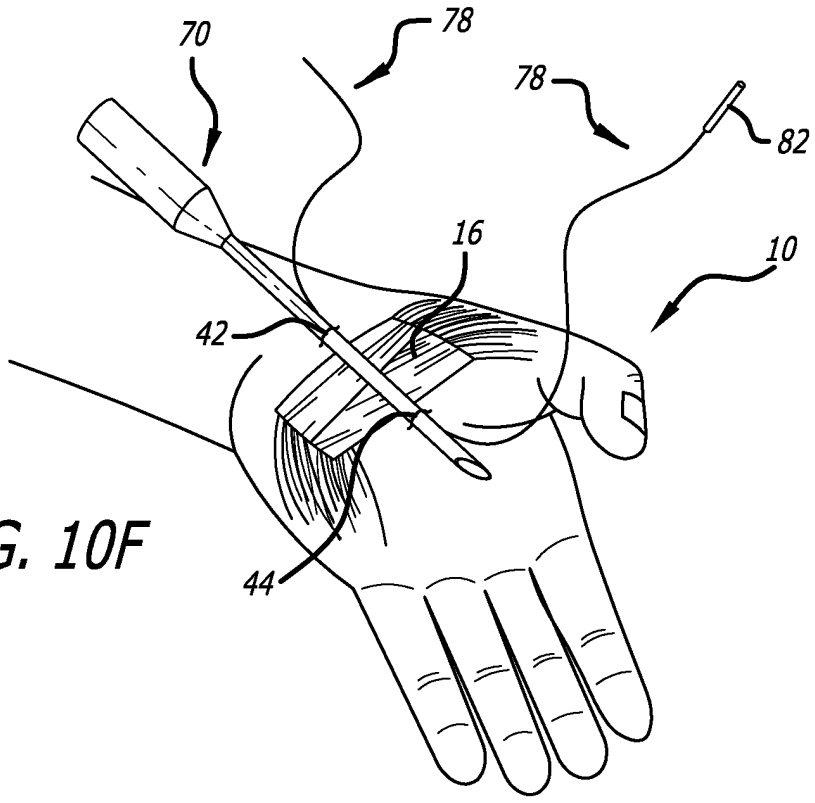


FIG. 10F

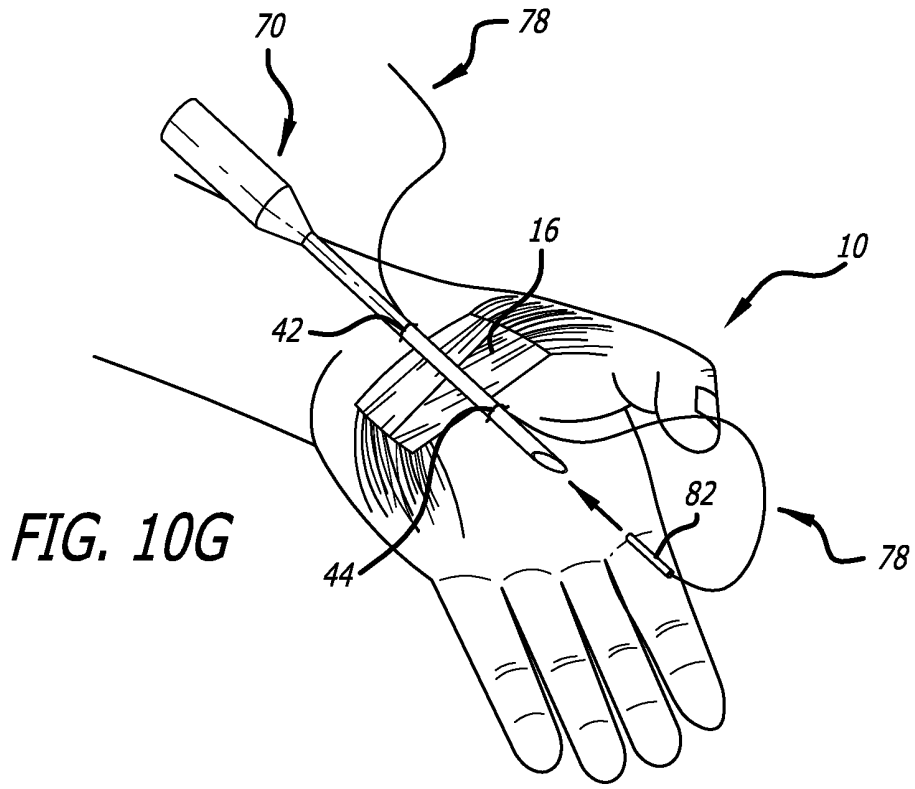


FIG. 10G

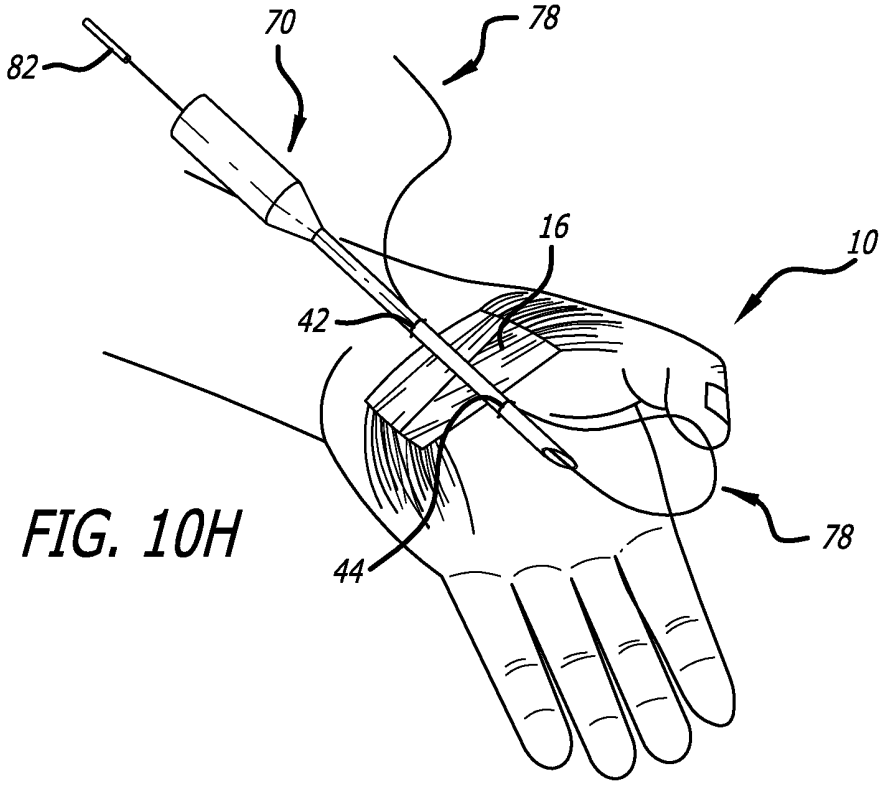


FIG. 10H

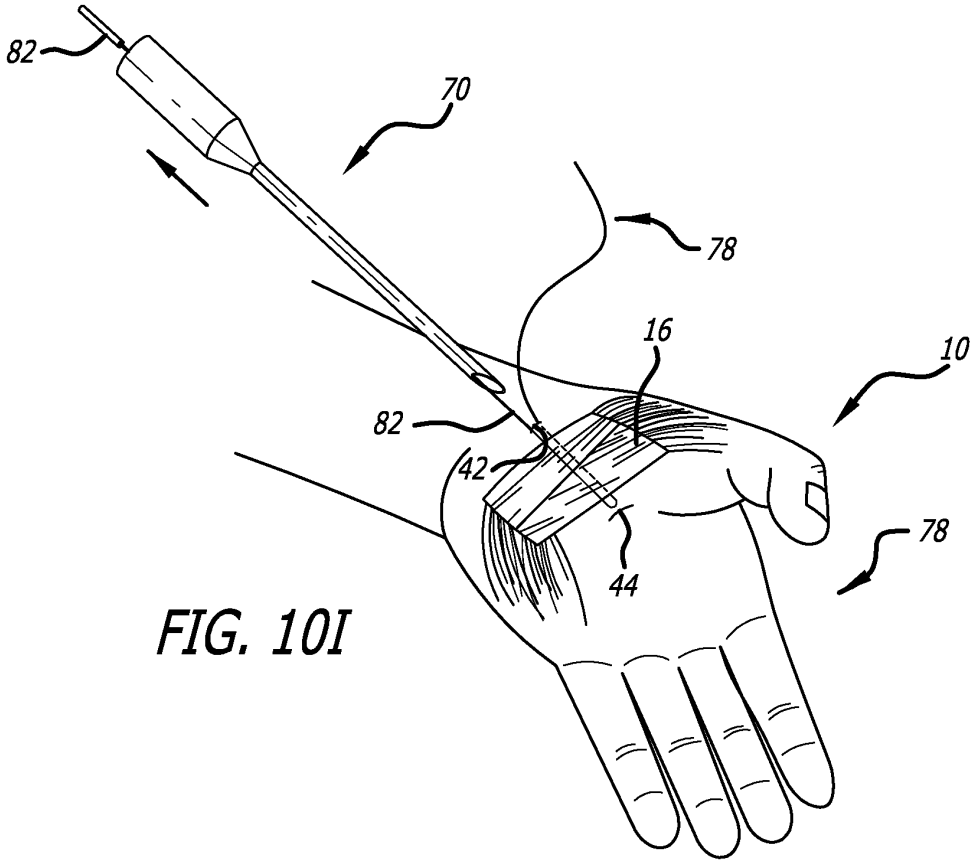


FIG. 10I

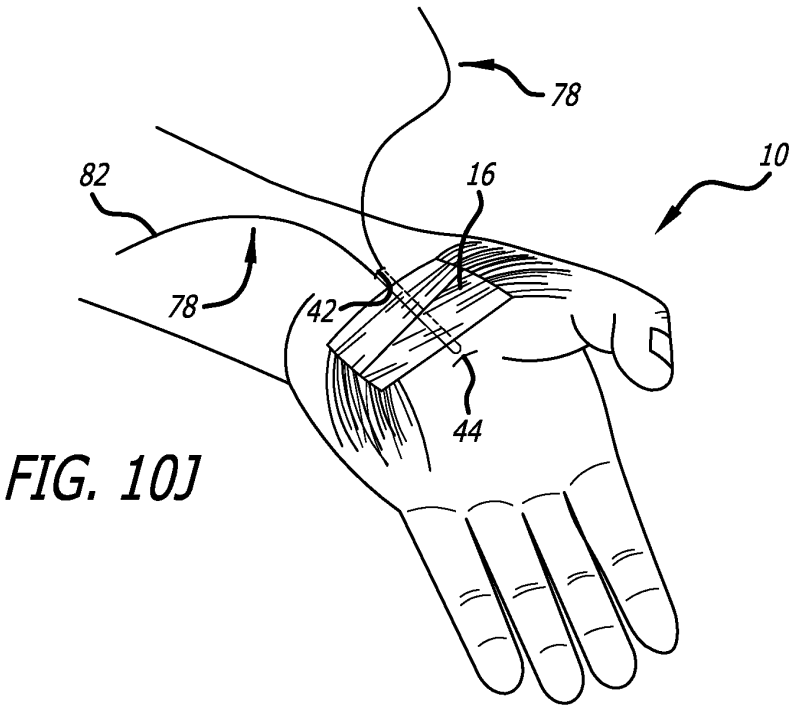


FIG. 10J

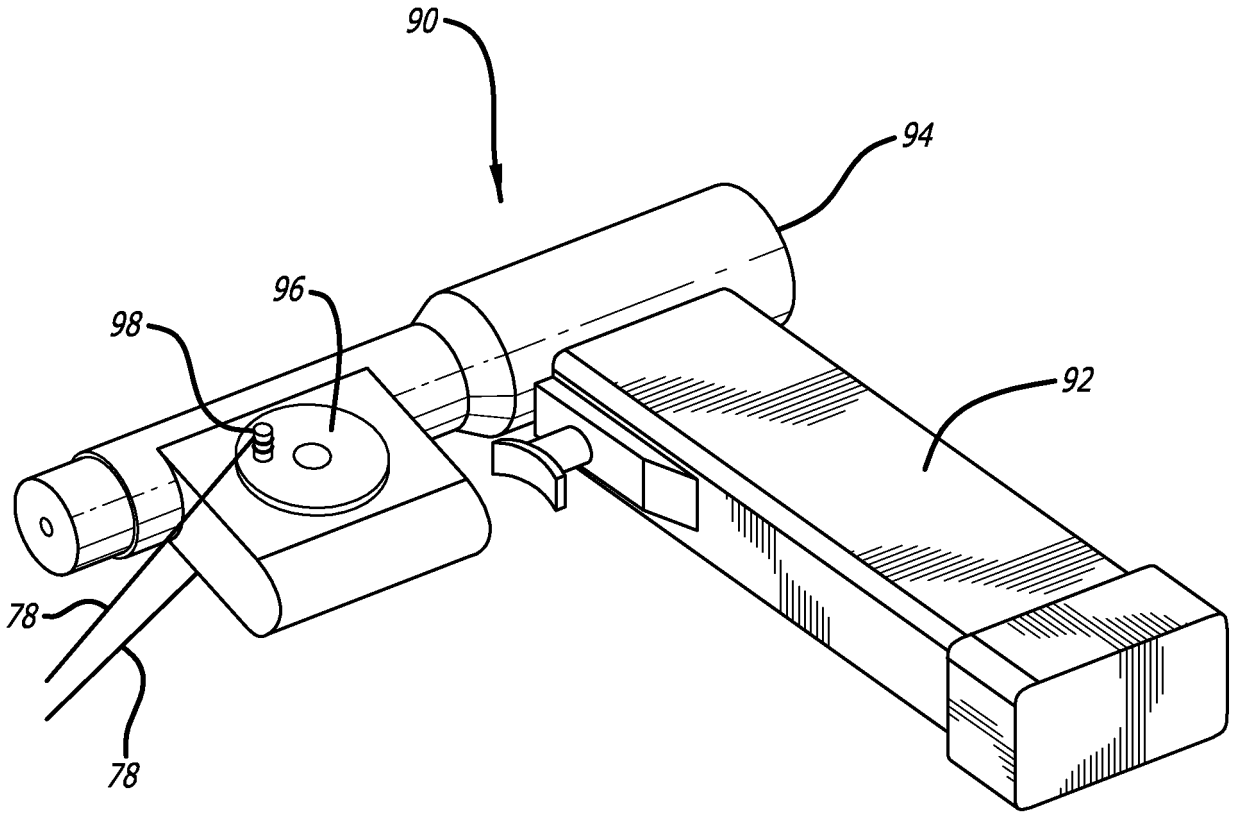


FIG. 11

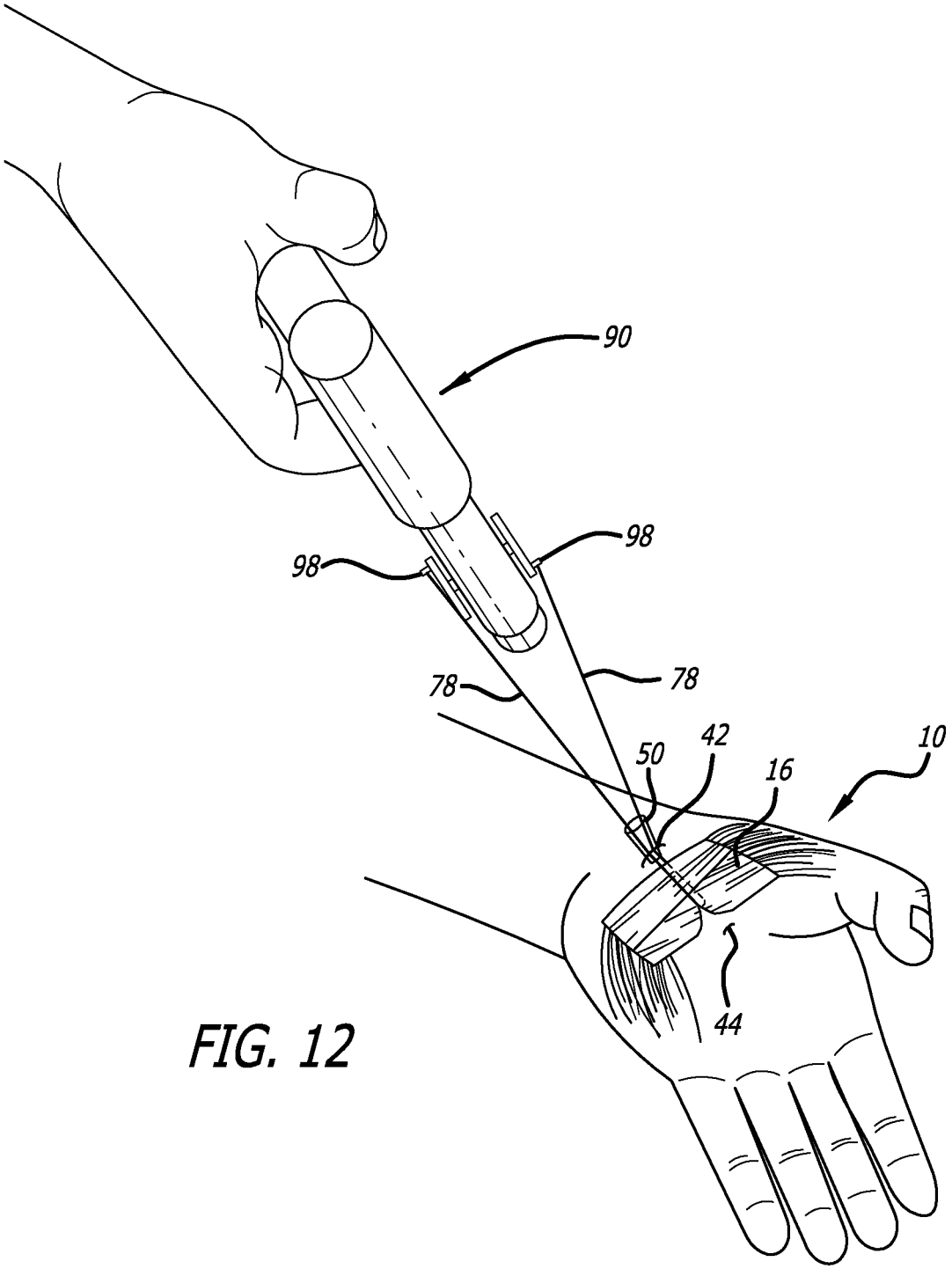


FIG. 12

REFERENCES CITED IN THE DESCRIPTION

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- US 5522827 A **[0008]**
- WO 2011140206 A **[0009]**